Exhibit 1

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May 11, 2020

VIA ECF
Clem C. Trischler
Pietragallo Gordon Alfano Bosick & Raspanti, LLP
38th Floor, One Oxford Centre
Pittsburgh, PA 15219

Re: IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION
Civil No. 19-2875 (RBK/JS)

Dear Mr. Trischler:

I am writing in response to your May 8, 2020 letter with regard to Defendants' request to make significant changes to the agreed search terms that were ordered by the Court following a lengthy meet and confer process. First, thank you for confirming that the information provided in your letter provides "the most reliable and updated information," you have obtained or provided to date. Based on the information you have provided, it is clear that Plaintiffs can only agree to a segment of the proposed modifications. As set forth in great detail below, the balance of your proposed modifications are unacceptable, and raise significant concerns as to the pace and methods followed to date by the Defendants in fulfilling their ESI obligations in this litigation.

As you have repeatedly prefaced your letters with a historical synopsis, we would like to provide a more accurate summary of how we have reached this point. In the months leading up to

the December status conference, per the Court's instructions, Plaintiffs negotiated search terms with Defendants, primarily with counsel for ZHP. This is an important point, since ZHP has been absent from the discussions since January, and has apparently not participated at all in the direct analysis of ESI that you describe in your letter. The negotiation leading up to the Order memorializing the agreed search terms was fruitful, despite Defendants' refusal to conduct test collections and searches to inform the negotiations, and the parties were able to agree to search terms, modifiers, and a procedure for addressing issues that might arise. During January, Plaintiffs negotiated translated versions of those terms for use by ZHP in its search of Chinese language documents.

On January 16, 2020, Mylan's counsel sent an e-mail to Plaintiffs stating: "Mylan has identified a few **discrete issues** related to the plaintiffs' custodial search terms that have arisen during the document collection process. I would like to discuss these issues with you. Please let me know if you have some availability for a call with me early next week." (emphasis added). The issue was raised only on behalf of Mylan.

Plaintiffs had a meet and confer call with Mylan on January 21, 2020, wherein Mylan identified a few discrete issues specific to Mylan's collection of documents, for example a term that was appearing in an e-mail footer. Plaintiffs agreed to modifications to the search terms to address those issues, such as including an excluder modifier containing specific language from the footer in order to exclude documents that only hit because of the footer. One of the other issues raised by Mylan on the January 21, 2020 call was that the "Other Drug Names" modifier, which would serve to exclude documents that only addressed irrelevant drugs, was not workable for Mylan because Mylan manufactures thousands of drugs. Plaintiffs responded by asking if Mylan could look into narrowing the drugs on the list based upon the drugs that the specific custodians

worked on, as it seemed unlikely that the custodians at issue had worked on all of the thousands of drugs manufactured by Mylan. Plaintiffs left the call with the understanding that Mylan was going to provide a concrete proposal for such discrete modifications, along with answers to Plaintiffs' questions. Again, this discussion only addressed the handful of discrete issues raised by Mylan with regard to Mylan's collection of documents.

Plaintiffs then heard nothing from Mylan until March 19, 2020, two months later, when Mylan proposed a massive wholesale revision of the agreed to and ordered search terms, including elimination of entire categories of search terms ("we have also eliminated the authors and inspectors tab"), and radical modifications to other entire categories of search term ("other primary terms have been modified more broadly by amending the modifier terms where entire categories of modifiers are still being run against entire sets of primary terms, as well as by adding a proximity limitation"). Plaintiffs responded the same day stating our position that a wholesale revision of the agreed search terms was not appropriate, especially where the issues were being raised so late in the process, but that Plaintiffs were still willing to meet and confer as we believed the Court would expect us to do so regardless of the facial impropriety of the request.

In the course of further back and forth communications, Plaintiffs e-mailed Mylan on March 26, 2020, and requested additional information needed to understand the purported basis for Mylan's request. In response, on March 31, 2020 Mylan only provided a "redline" intended to contrast their proposal against the ordered search terms. This redline was very difficult to decipher because it did not actually track the format of the ordered search terms. On April 15, 2020 Mylan provided two spreadsheets containing raw hit counts for the ordered terms and Mylan's revised proposal. These, again, were not very helpful, as they were run without any attempt at determining unique hits (that is, the number of hits that did not already hit another term), and prior to any de-

duplication and e-mail threading having been performed, significantly inflating the total number of documents and gigabytes of actual unique documents that would have to be reviewed. Mylan continued to ignore the remainder of Plaintiffs' data requests from their March 26, 2020 e-mail, which Plaintiffs again re-iterated to Mylan was necessary to evaluate Mylan's request for modifications.

Finally, on just last Friday, May 8, at 8:45pm Eastern Time, Mylan provided some more detailed information responsive to the questions Plaintiffs had been asking since mid-March. From that delay in responding, it appears that Mylan had not collected that information, which was basic and should have been provided with the initial request to modify the search terms, when Mylan first proposed the wholesale revision of the ordered search terms in March. A detailed response to the information and proposal made on May 8 is below.

Overarching issues

A few overarching issues need to be addressed prior to Plaintiffs' detailed response to the specific items issue.

First, Plaintiffs are very concerned that Mylan states it has not provided documents to its E-discovery vendor for processing. This is a striking revelation, as it was assumed that the E-discovery vendors for each Defendant were actively collecting and processing documents as of early January, 2020 in accordance with all reasonable expectations. In this context, please advise as to the identity of Mylan's and all other Defendants' E-discovery vendors, and which have placed the collections on their platforms. In the context of your requests we believe it is reasonable to ask these questions.

Please also confirm whether or to what extent Mylan and the other Defendants have provided the subsets of documents resulting from their proposed revised search terms to their

vendors for processing and have begun review of those documents for production under the Court's revised schedule. Please advise of the status of these collections and reviews of custodial documents.

Second, the data provided regarding search terms and status of review is Mylan specific. We have not received any such data or justification for modification from any other Defendant, and particularly, have not received any such information from ZHP, who took the lead in negotiating the search terms. We are similarly very concerned that these other Defendants may not have yet begun the processing and review of their custodial documents. If the other Defendants have not performed this analysis in good faith, this appears to be nothing more than an opportunistic effort to deprive Plaintiffs of documents that are ordered to be identified and produced, based on the say so of another Defendant. Since Mylan appears to be taking the lead on this topic, please let us know, by Defendant, the status of their processing and review, as well as why those other Defendants believe Mylan's results are representative for their custodians (for example, Plaintiffs have agreed with ZHP as to the list of "Other Drug Names," so that should not be an issue for ZHP, and should significantly affect and reduce the number of documents being returned by ZHP).

Third, Plaintiffs are very concerned that the data produced by Mylan is very misleading since **no de-duplication and e-mail threading has yet been performed**. The ability by Defendants to use both vertical and horizontal de-duplication was a significant concession made by Plaintiffs during the negotiation of the ESI protocol in order to reduce the volume of documents Defendants would have to manually review. The failure to implement that concession likely results in a significant inflation of the document numbers and size of documents Defendants will actually have to manually review. The failure to implement these central processes codified in the

ESI protocol, along with many of the other issues set forth below, arguably amounts to "fixing the deck" before dealing the cards. Perhaps you were not aware of the significance of these issues, and hopefully following your review of this letter you will reevaluate the issues you have raised.

Fourth, your letter defines responsiveness by comparison to the Rule 34 document requests. While there will certainly be overlap, that is not the standard, and relevant documents might not clearly fall within the non-custodial document categories which are geared to identifiable categories and tranches of documents, rather than the wide range of communications and attachments that are found in custodial files.

Response Focused on Specific Issues

Plaintiffs asked Plaintiffs' ESI expert Jonathan Jaffe to review and analyze the differences between the "Original ESI Search Terms" and the "Revised ESI Search Terms" as detailed by Mylan. The resulting analysis demonstrates that Mylan's May 8, 2020 letter omits a great deal of critical information and is unfortunately misleading. For example, while focusing attention on volume and burden, Mylan[1] quietly revised and removed search terms and modifiers that were the most likely to yield relevant, responsive documents.

In presenting the "Revised ESI Search Terms," Mylan implies that the restriction to or elimination of terms that are "facially overbroad" is the primary driver behind the reduction in "hit counts" from the "Original ESI Search Terms" as agreed to by the parties and ordered by the Court. The 12 terms Mylan selects for analysis are a red herring, designed to distract Plaintiffs and the Court from which terms are really being eliminated and why.

Setting aside the sample and returning to the actual proposal (the "Revised ESI Search Terms"), the terms Defendants are seeking to strip out are clearly core to the case.

[1] And to the degree that other Defendants are presenting Mylan's proposal as their own, all Defendants.

The following data demonstrates how the "Revised ESI Search Terms" alter the results:

1) Hit Counts on the Court ordered "Original ESI Search Terms" hereto attached as Exhibit ____ (Plaintiffs' Primary Terms (Hit Counts).xlsx).
2) Hit Counts on Mylan's proposed primary "Revised ESI Search Terms" hereto attached as Exhibit ____ (PGABR Primary Terms Counter-Proposal (Hit Counts).xlsx).
3) Hit Counts on Mylan's proposed modifiers for the primary "Revised ESI Search Terms" hereto attached as Exhibit ____ (PGABR Modifier Terms Counter-Proposal.xlsx).
4) A redlined pdf outlining differences between what Mylan has designated as the "Original ESI Search Terms" and "Revised ESI Search Terms" hereto attached as Exhibit ____ (Redline Comparison Search Term Proposals.pdf).

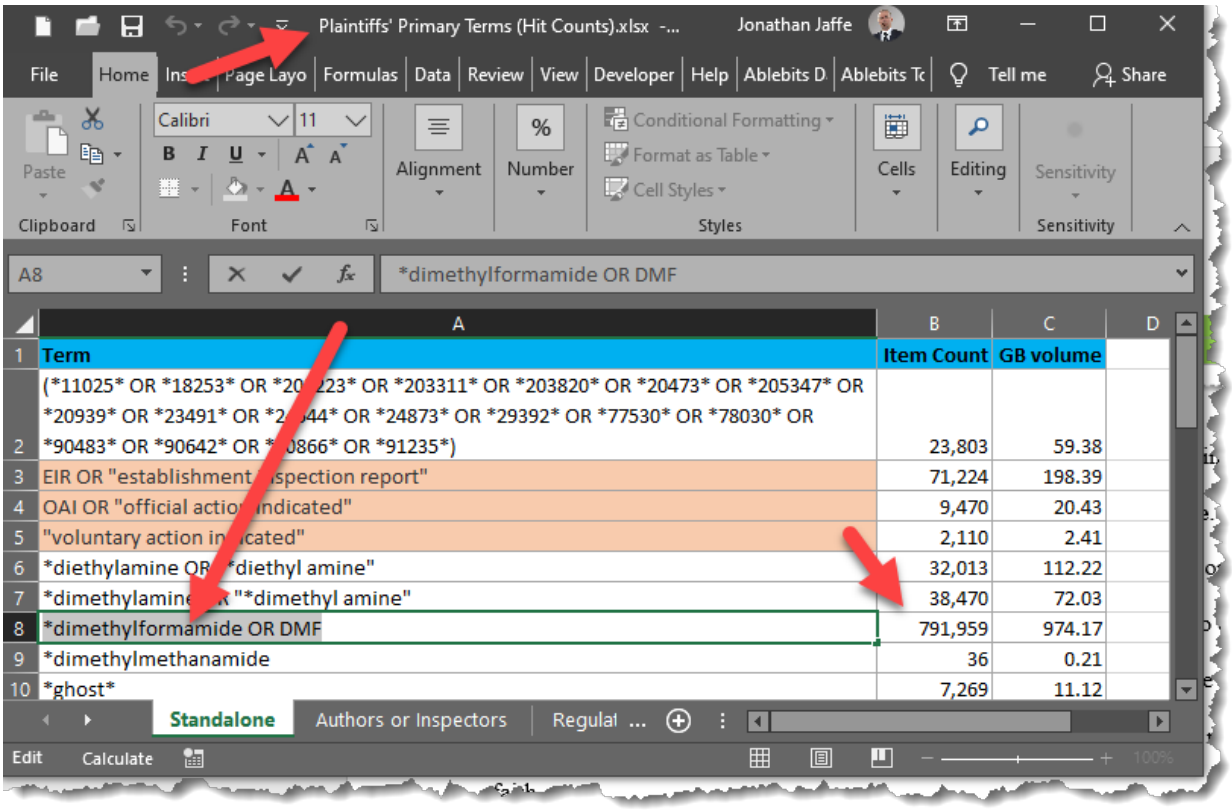
The following is by no means a comprehensive review of each and every term modification as proposed by Mylan. Nor do Plaintiffs lay out herein each and every objection. Except where noted, Plaintiffs reject all of the revisions to the Court ordered terms.

Standalone Search Terms

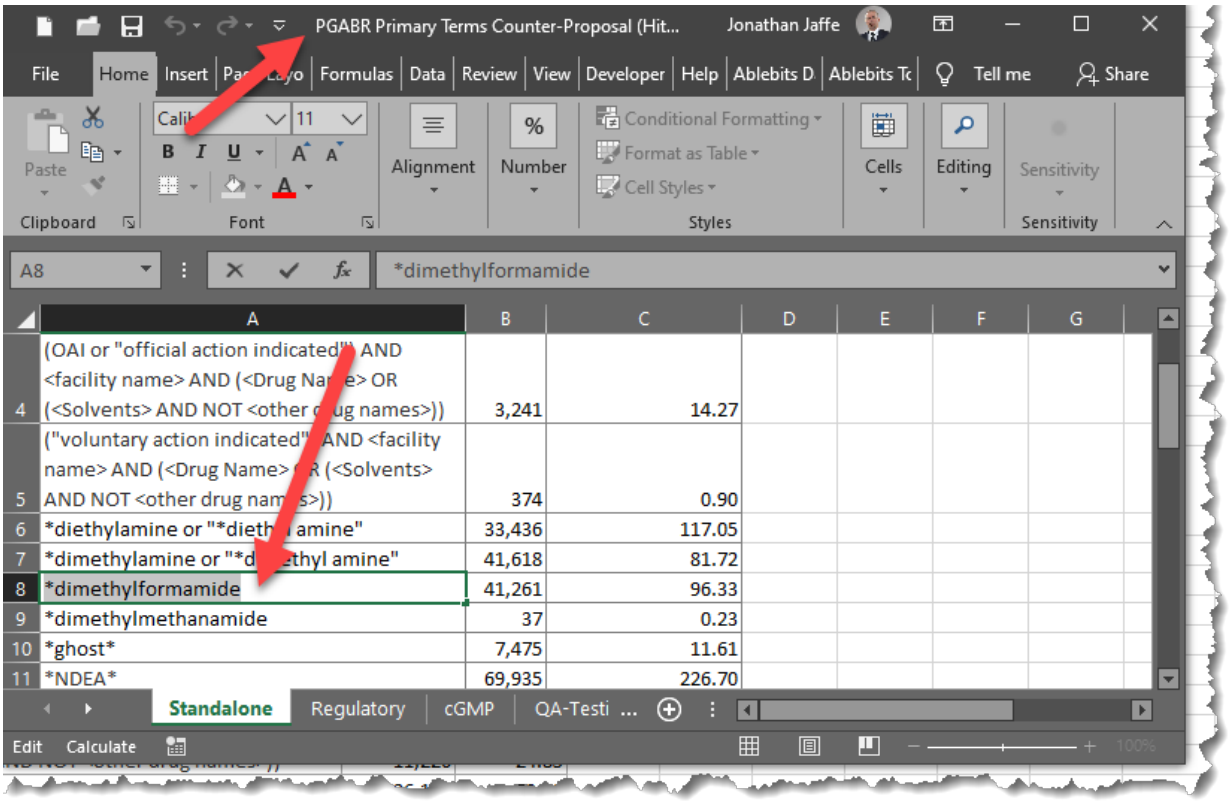
Perhaps the most egregious modification was the removal of the standalone term **DMF**. Standalone terms are considered by Plaintiffs to be so core to the case that if a document contains the standalone term, it is considered responsive. In the Court ordered terms, "Original ESI Search Terms," **DMF** appears on the first page of terms as ***dimethylformamide OR DMF**.

Mylan and the Court will recall that **DMF** is the commonly used abbreviation for one of the solvents that has been identified as causing the presence of NDMA in Valsartan.

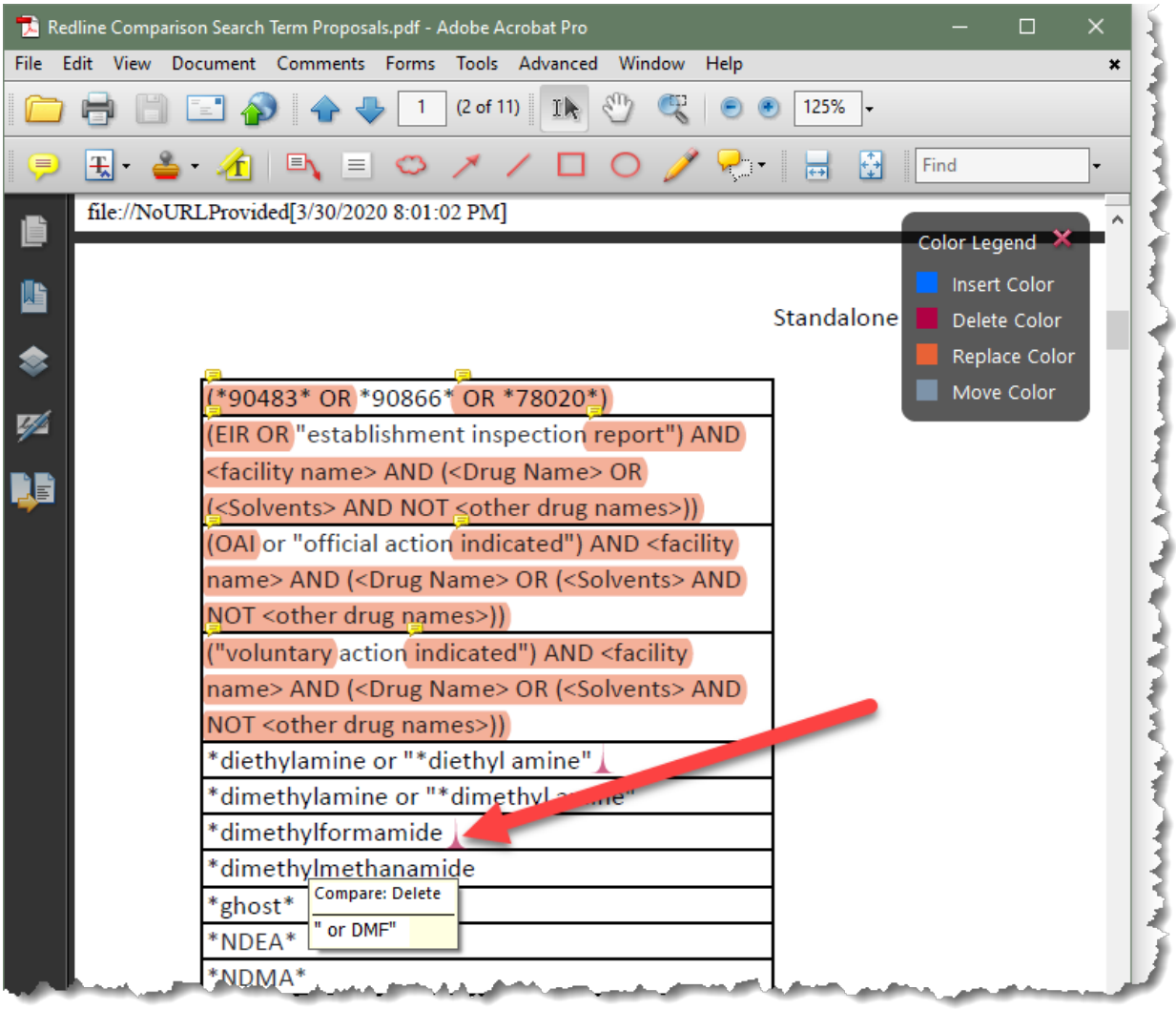
In Mylan's hit counts on the Court ordered terms, Mylan noted that including **DMF** doubled the 'hit count' on the standalone terms.



Mylan did not discuss the elimination of DMF, but rather just eliminated **DMF**, only keeping ***dimethylformamide**. To Plaintiffs' knowledge, Mylan chose to eliminate the 500,000+ documents that "hit" on **DMF** simply to reduce the overall number of hits. To Plaintiffs' knowledge, Mylan did no due diligence to determine that those documents were not responsive, nor did they propose any modifiers to better refine the term. Nor did Mylan sample **DMF** in their list of 12 Primary Search Terms. This and similar proposed changes greatly concern us.



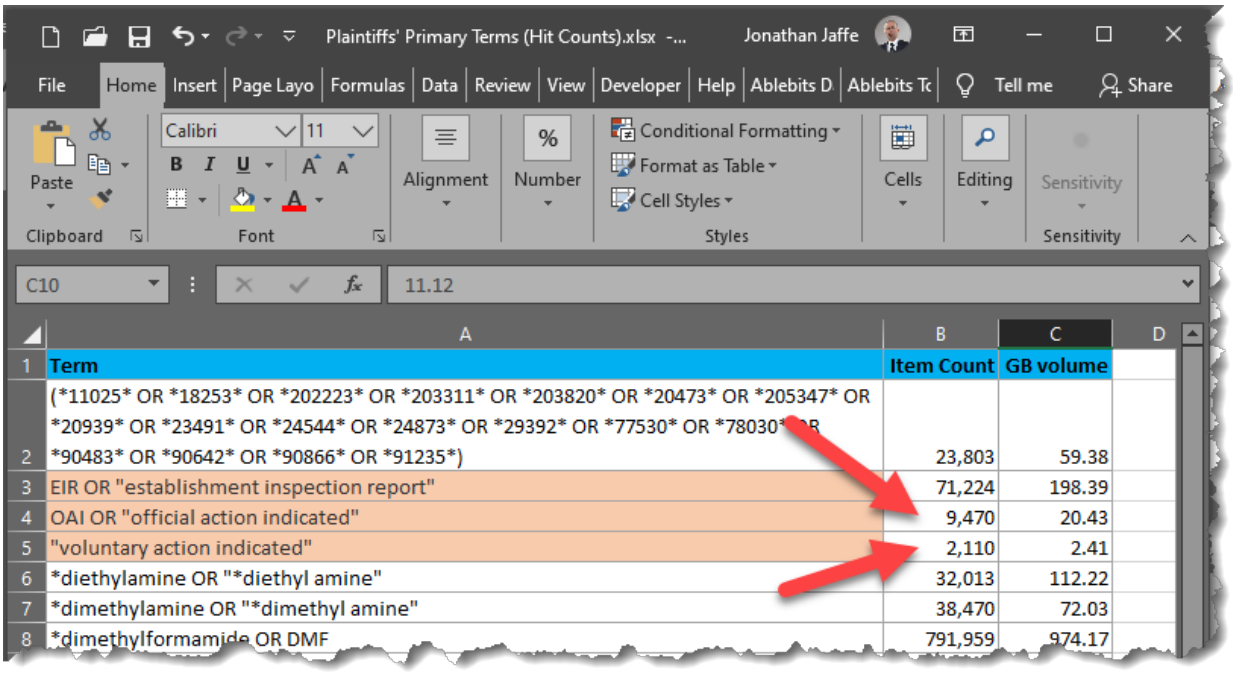
	A	B	C
4	(OAI or "official action indicated") AND <facility name> AND (<Drug Name> OR (<Solvents> AND NOT <other drug names>))	3,241	14.27
5	("voluntary action indicated") AND <facility name> AND (<Drug Name> OR (<Solvents> AND NOT <other drug names>))	374	0.90
6	*diethylamine or "*diethyl amine"	33,436	117.05
7	*dimethylamine or "*dimethyl amine"	41,618	81.72
8	*dimethylformamide	41,261	96.33
9	*dimethylmethanamide	37	0.23
10	*ghost*	7,475	11.61
11	*NDEA*	69,935	226.70



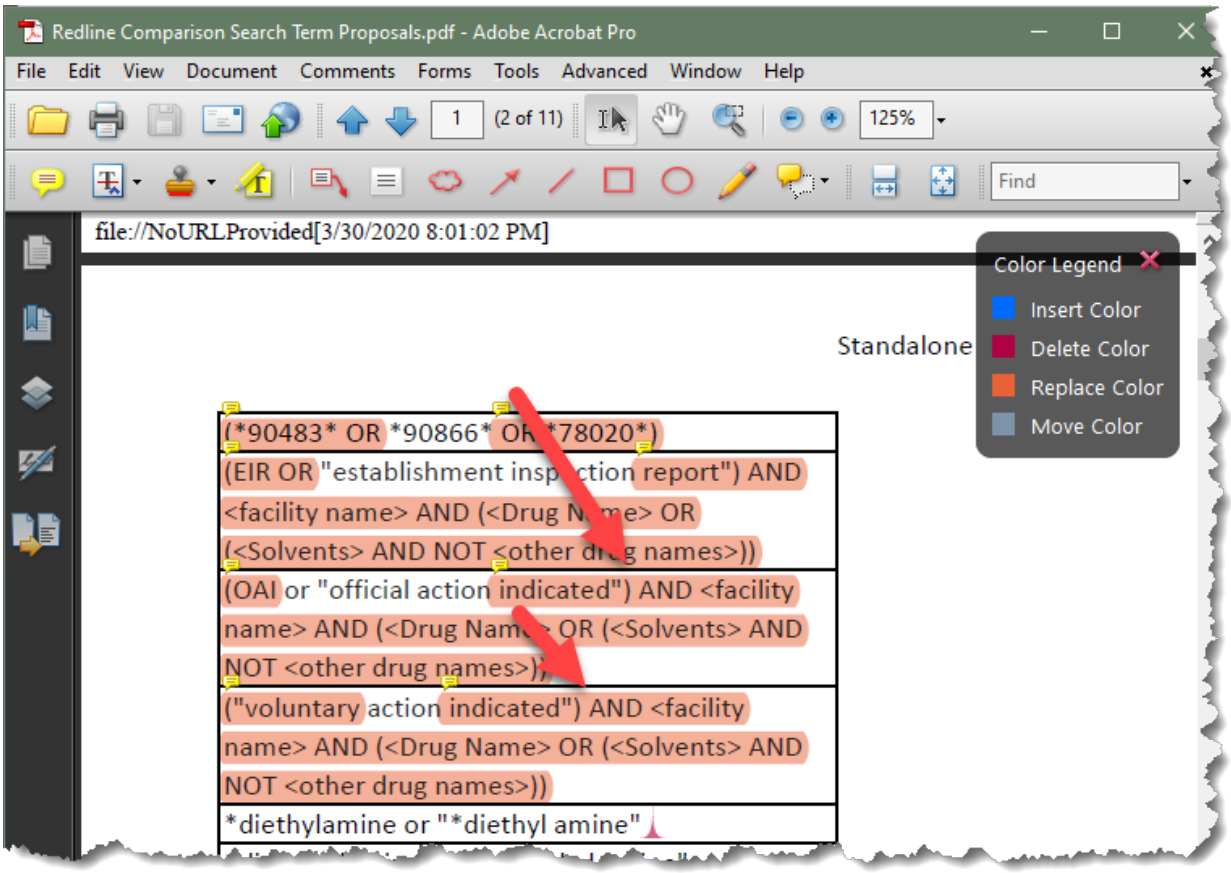
The omission of **DMF** was not the only modified standalone term with which Plaintiffs have a serious issue. Others include: (1) The quiet removal of a host of agreed upon numbers Defendants have acknowledged that Defendants used to refer to Valsartan; (2) the restriction of Establishment Inspection Reports to drug names when Defendants are well aware that these reports apply to the facility and not the drug and that the list of facility names is incomplete; (3) the restriction of 483 letters, and other FDA actions, to drug names and facility names for multiple reasons including that Defendants are well aware these letters apply to the entire facility — Mylan's own counts show low document counts for OIA and VAI's; and (4) the restriction of

genotoxicity and carcinogenicity and variations to drug name or solvent are all core issues to the case.

Indeed, none of these changes are discussed nor justified in Mylan's letter of May 8th.



	A	B	C	D
1	**Term**	**Item Count**	**GB volume**	
	(*11025* OR *18253* OR *202223* OR *203311* OR *203820* OR *20473* OR *205347* OR *20939* OR *23491* OR *24544* OR *24873* OR *29392* OR *77530* OR *78030* OR			
2	*90483* OR *90642* OR *90866* OR *91235*)	23,803	59.38	
3	EIR OR "establishment inspection report"	71,224	198.39	
4	OAI OR "official action indicated"	9,470	20.43	
5	"voluntary action indicated"	2,110	2.41	
6	*diethylamine OR "*diethyl amine"	32,013	112.22	
7	*dimethylamine OR "*dimethyl amine"	38,470	72.03	
8	*dimethylformamide OR DMF	791,959	974.17	



Drug Modifier Terms

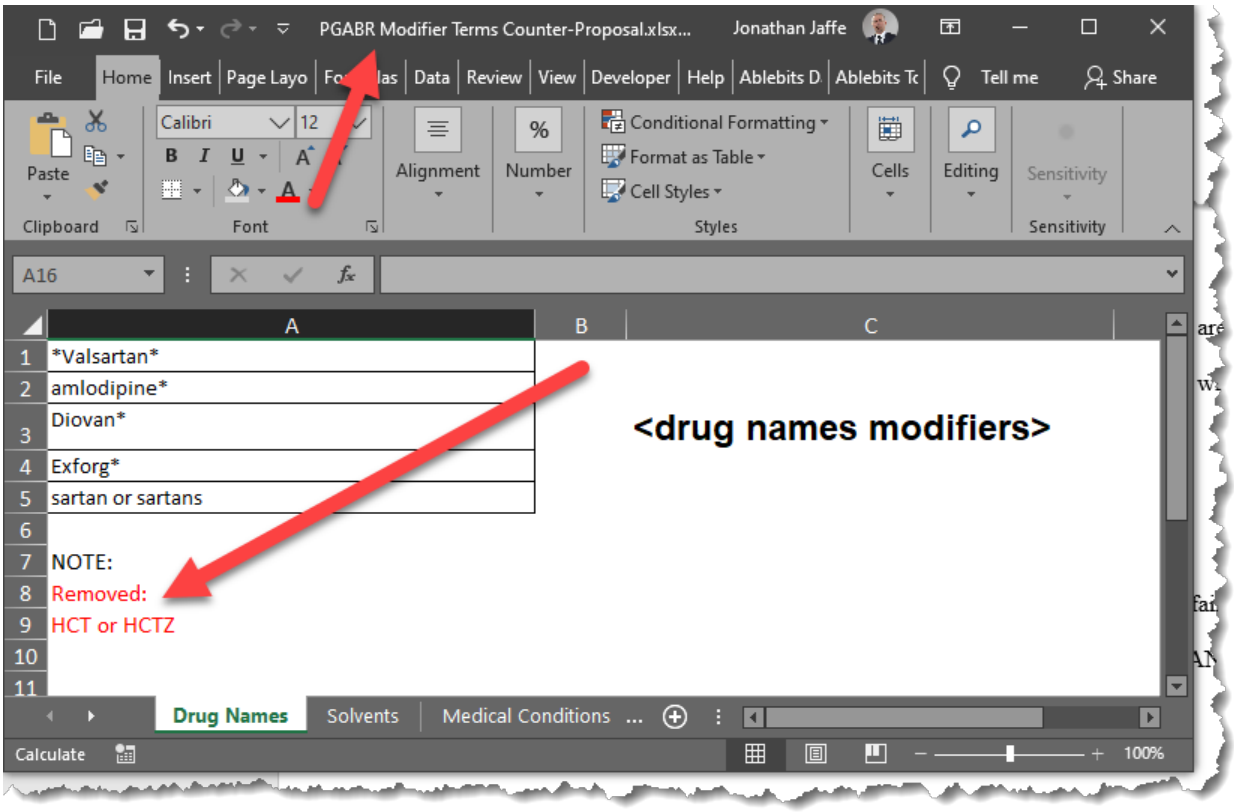
DMF is hardly the only instance of Mylan removing a key term.

As the Court and Mylan and Defendants know, the vast number of terms are not standalone. Rather, for a "hit" to appear, these terms must appear in conjunction with a Drug Name, a Solvent, or other "modifier" terms.

Most egregiously, Mylan removed **HCT** and **HCTZ** from the list of drug names. The Court and Mylan are well aware that **HCT/HCTZ** or **hydrochlorothiazide** is the diuretic that is part of the Valsartan combination tablet. Going back to **Defendants'** proposals from last November, **HCT** and **HCTZ** were already agreed to previously by Defendants as relevant. Mylan made no attempt to introduce **HCT** or **HCTZ** into any of the other term lists to compensate for removing them from the list of drug name modifiers. To Plaintiffs' knowledge, Mylan conducted no analyses to

determine that the removal of these terms would not substantially impact the production of responsive, relevant documents.

Since the drug names are modifier terms, this one change impacts across every search term excepting the standalone terms. This was not a change highlighted in Mylan's letters or other communications.



Regulatory Terms

On the Regulatory set, Mylan noted that **inspect*** and **investigat*** had a fair number of hits. These terms were not standalone, but were modified already with <Term> AND (<Drug Name> OR (<Solvents> AND NOT <other drug names>) OR <regulatory modifiers> OR <facility names>).

13	inspect*	682,542	1,157.12
14	investigat*	780,241	1,331.20

Mylan's new proposal reduces the 'hit count' by changing these to **<Term> /50 <Drug Name>**. That means that inspections of the solvents, inspections by the regulatory agencies, and facility inspections would no longer hit on these terms.

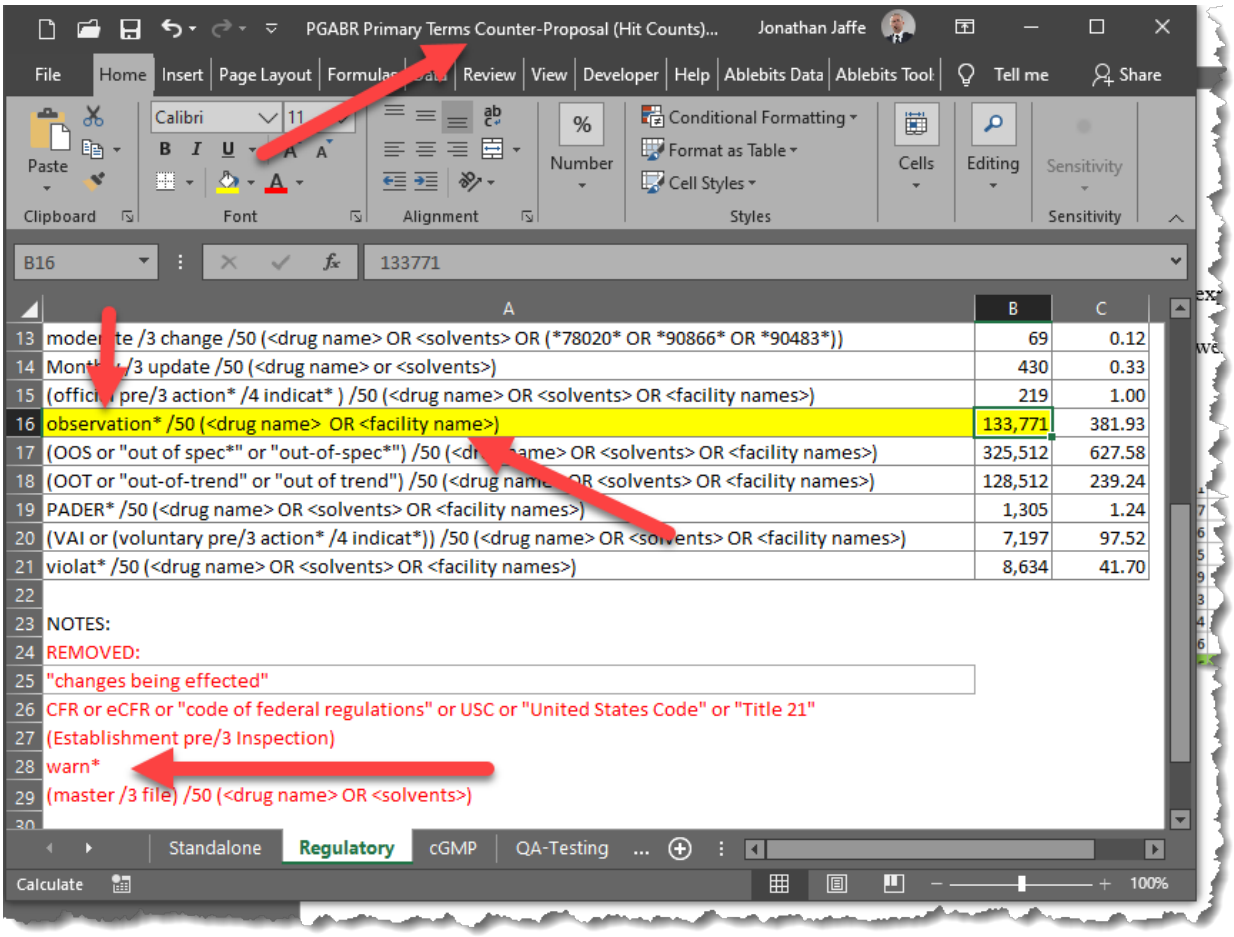
inspect* /50 <drug name>
investigat* /50 <drug name>

In Mylan's sample set of 12 terms from the May 8th letter, these two terms both had a fair number of "true" hits that would have been missed by restricting them to within 50 words of the drug names.

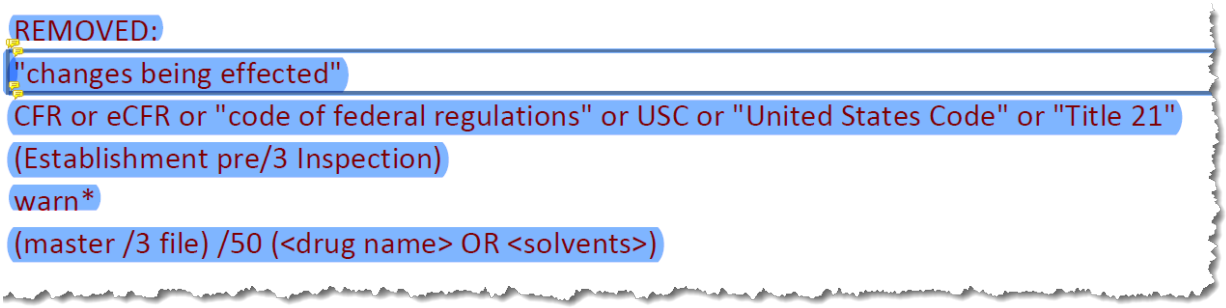
Inspect	682,542	August 2019	1,366	100	**13**	**4**	**9**
Investigat*	780,241	June 2014	2,509	100	**6**	**6**	**0**

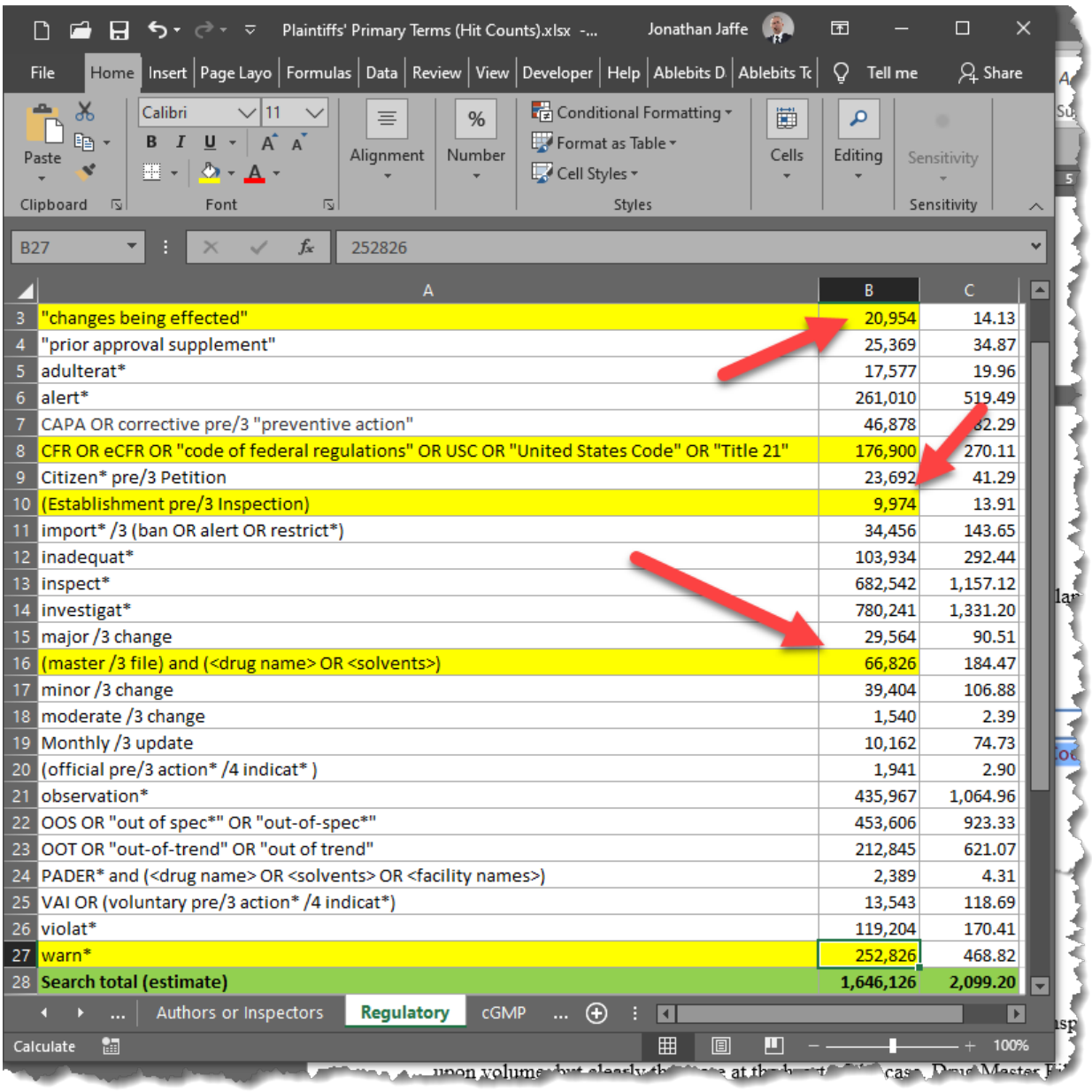
In a similar manner, Mylan noticed a larger hit count with **observation**, but here inexplicably Mylan's proposal now includes a facility modifier. The term **warn*** (key to FDA warnings) was removed entirely.

21	observation*	435,967	1,064.96
22	OOS OR "out of spec*" OR "out-of-spec*"	453,606	923.33
23	OOT OR "out-of-trend" OR "out of trend"	212,845	621.07
24	PADER* and (<drug name> OR <solvents> OR <facility names>)	2,389	4.31
25	VAI OR (voluntary pre/3 action* /4 indicat*)	13,543	118.69
26	violat*	119,204	170.41
27	warn*	252,826	468.82



There are multiple inconsistencies in the implied representation by Mylan that Mylan was solely focused on terms with large hit counts. For example:





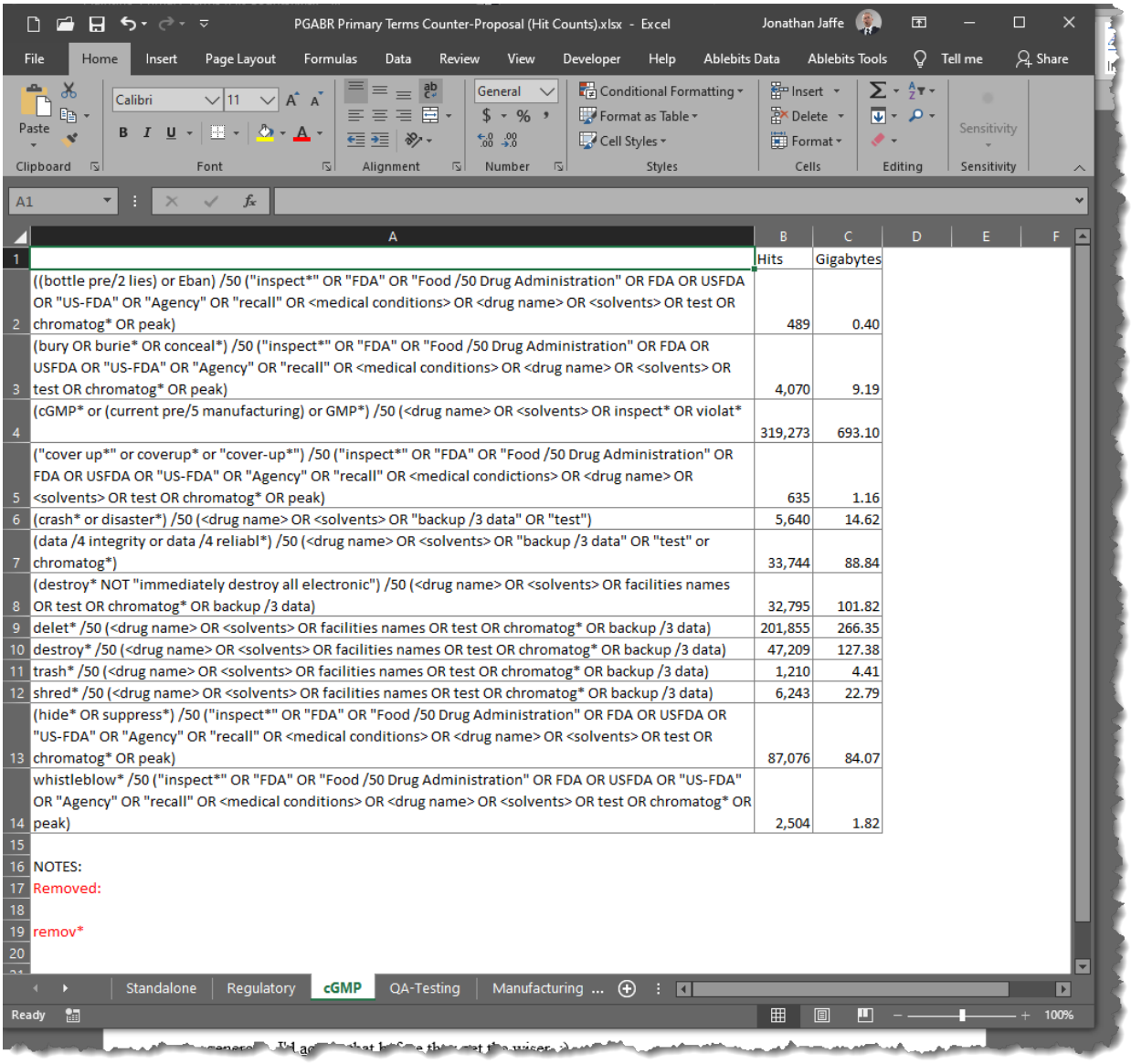
	A	B	C
3	"changes being effected"	20,954	14.13
4	"prior approval supplement"	25,369	34.87
5	adulterat*	17,577	19.96
6	alert*	261,010	519.49
7	CAPA OR corrective pre/3 "preventive action"	46,878	82.29
8	CFR OR eCFR OR "code of federal regulations" OR USC OR "United States Code" OR "Title 21"	176,900	270.11
9	Citizen* pre/3 Petition	23,692	41.29
10	(Establishment pre/3 Inspection)	9,974	13.91
11	import* /3 (ban OR alert OR restrict*)	34,456	143.65
12	inadequat*	103,934	292.44
13	inspect*	682,542	1,157.12
14	investigat*	780,241	1,331.20
15	major /3 change	29,564	90.51
16	(master /3 file) and (<drug name> OR <solvents>)	66,826	184.47
17	minor /3 change	39,404	106.88
18	moderate /3 change	1,540	2.39
19	Monthly /3 update	10,162	74.73
20	(official pre/3 action* /4 indicat*)	1,941	2.90
21	observation*	435,967	1,064.96
22	OOS OR "out of spec*" OR "out-of-spec*"	453,606	923.33
23	OOT OR "out-of-trend" OR "out of trend"	212,845	621.07
24	PADER* and (<drug name> OR <solvents> OR <facility names>)	2,389	4.31
25	VAI OR (voluntary pre/3 action* /4 indicat*)	13,543	118.69
26	violat*	119,204	170.41
27	warn*	252,826	468.82
28	**Search total (estimate)**	**1,646,126**	**2,099.20**

Clearly, the removal of (**master /3 files**) or (**Establishment pre/3 Inspection**) reports cannot be based upon volume because the volume is relatively speaking notably lower than nearly all other terms (only 9,974 hits on **Establishment pre/3 Inspection**!), but clearly these are at the heart of the case. Plaintiffs had even modified the **Establishment pre/3 Inspection** in an earlier negotiation upon Defendant's request to require the word **Establishment** to come before the word **Inspection**. Drug Master Files contain all of the manufacturing data, failure plans, process

documentation, testing, etc. Equally core to the case would be any email instruction telling someone not to put data or test results into the Drug Master File. The removal of these terms was relegated to a footnote in the redline provided by Mylan. It was omitted from Mylan's letter of May 8th. Mylan did not otherwise highlight or discuss reasoning for excluding these terms. To Plaintiffs' knowledge, the inclusion of these terms was not subjecting Mylan to disproportionately unanticipated additional burden. Plaintiffs are concerned that Mylan (and Defendants) are using 'hit count' merely as a pretext for removing well-tailored terms reasonably calculated to hit on responsive, relevant documents. These are hardly the signs of good faith negotiation particularly when the search terms have already been agreed upon and ordered by the Court, especially in the absence of de-duplication and email threading.

In the same footnote, Mylan included a change where **CAPA or corrective pre/3 "preventative action"** was moved to the QA-Testing tab. That is a subtle change, but effectively removes any **CAPA or corrective pre/3 "preventative action"** which refers to the facility or a regulatory agency but does not mention the drug or solvent specifically. Again, Mylan and the Court is aware that in a case of contamination, the manufacturing corrective and preventative actions potentially speak to the heart of the allegations.

cGMP (current Good Manufacturing Practice) Terms



PGABR Primary Terms Counter-Proposal (Hit Counts).xlsx - Excel

	A	B	C
1		Hits	Gigabytes
2	((bottle pre/2 lies) or Eban) /50 ("inspect*" OR "FDA" OR "Food /50 Drug Administration" OR FDA OR USFDA OR "US-FDA" OR "Agency" OR "recall" OR <medical conditions> OR <drug name> OR <solvents> OR test OR chromatog* OR peak)	489	0.40
3	(bury OR burie* OR conceal*) /50 ("inspect*" OR "FDA" OR "Food /50 Drug Administration" OR FDA OR USFDA OR "US-FDA" OR "Agency" OR "recall" OR <medical conditions> OR <drug name> OR <solvents> OR test OR chromatog* OR peak)	4,070	9.19
4	(cGMP* or (current pre/5 manufacturing) or GMP*) /50 (<drug name> OR <solvents> OR inspect* OR violat*	319,273	693.10
5	("cover up*" or coverup* or "cover-up*") /50 ("inspect*" OR "FDA" OR "Food /50 Drug Administration" OR FDA OR USFDA OR "US-FDA" OR "Agency" OR "recall" OR <medical condictions> OR <drug name> OR <solvents> OR test OR chromatog* OR peak)	635	1.16
6	(crash* or disaster*) /50 (<drug name> OR <solvents> OR "backup /3 data" OR "test")	5,640	14.62
7	(data /4 integrity or data /4 reliabl*) /50 (<drug name> OR <solvents> OR "backup /3 data" OR "test" or chromatog*)	33,744	88.84
8	(destroy* NOT "immediately destroy all electronic") /50 (<drug name> OR <solvents> OR facilities names OR test OR chromatog* OR backup /3 data)	32,795	101.82
9	delet* /50 (<drug name> OR <solvents> OR facilities names OR test OR chromatog* OR backup /3 data)	201,855	266.35
10	destroy* /50 (<drug name> OR <solvents> OR facilities names OR test OR chromatog* OR backup /3 data)	47,209	127.38
11	trash* /50 (<drug name> OR <solvents> OR facilities names OR test OR chromatog* OR backup /3 data)	1,210	4.41
12	shred* /50 (<drug name> OR <solvents> OR facilities names OR test OR chromatog* OR backup /3 data)	6,243	22.79
13	(hide* OR suppress*) /50 ("inspect*" OR "FDA" OR "Food /50 Drug Administration" OR FDA OR USFDA OR "US-FDA" OR "Agency" OR "recall" OR <medical conditions> OR <drug name> OR <solvents> OR test OR chromatog* OR peak)	87,076	84.07
14	whistleblow* /50 ("inspect*" OR "FDA" OR "Food /50 Drug Administration" OR FDA OR USFDA OR "US-FDA" OR "Agency" OR "recall" OR <medical conditions> OR <drug name> OR <solvents> OR test OR chromatog* OR peak)	2,504	1.82
15			
16	NOTES:		
17	Removed:		
18			
19	remov*		
20			

Standalone | Regulatory | cGMP | QA-Testing | Manufacturing ...

Ready

The cGMP terms are one area where Plaintiffs had previously acknowledged there may be legitimate concerns.

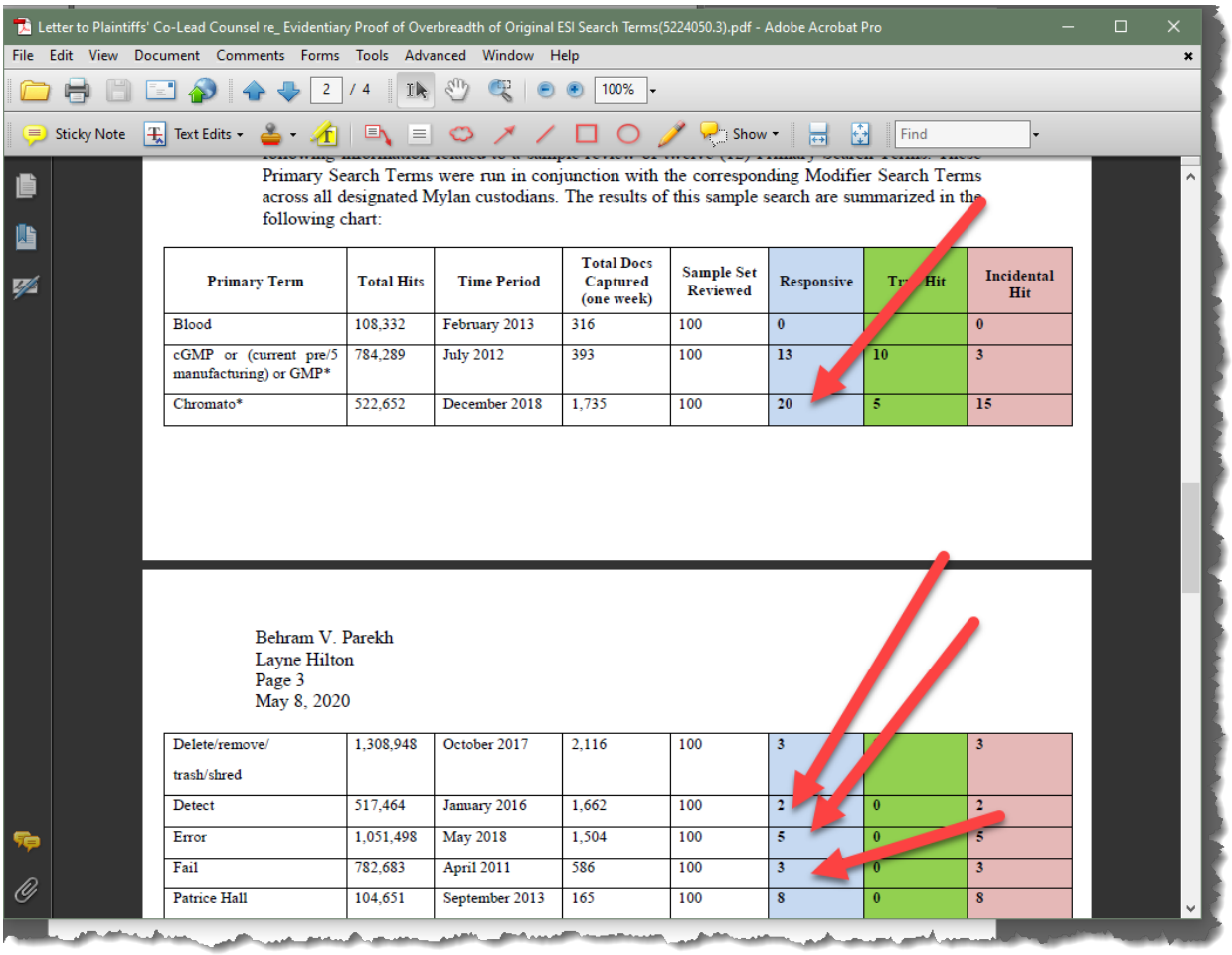
Mylan did raise legitimate examples with Plaintiffs in oral conversations that some of the terms were used in standard email footers. As set forth above, Plaintiffs proposed to use other wording in the email footers to construct a more tailored search that would effectively ignore these footers. Mylan did not adopt Plaintiffs' suggestion.

That being said, Plaintiffs are prepared to accept Mylan's proposed cGMP search term modifications with one change: wherever /50 is used as a proximity, /300 should be substituted.

Plaintiffs feel this is a reasonable modification requiring the term to appear within 1-2 paragraphs of the drug/solvent/etc. An average paragraph is 100-200 words.

QA-Testing Terms

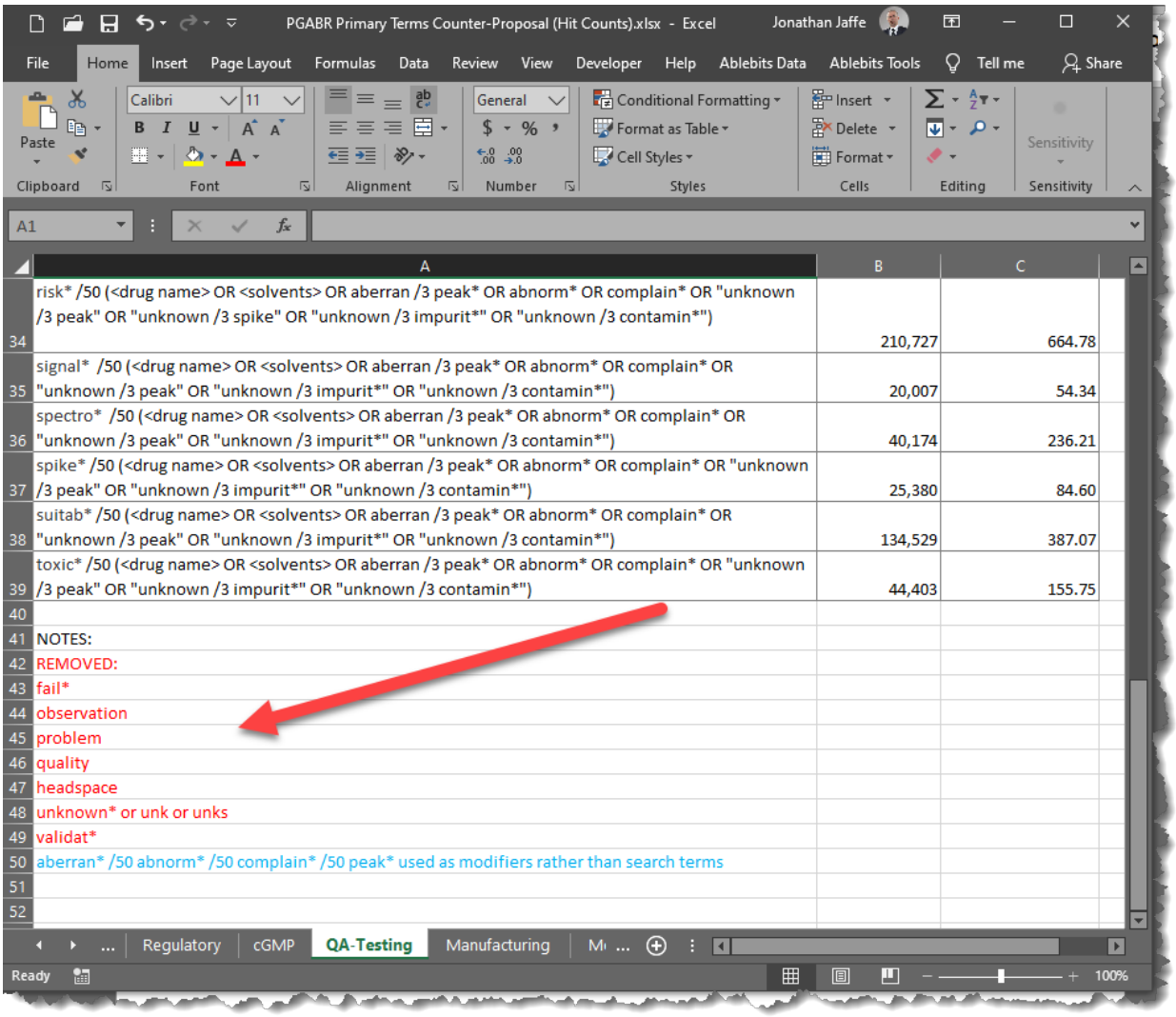
On the QA-Testing terms, Plaintiffs note two major sets of changes. (1) Almost all of the terms were changed to be proximate within a quarter paragraph to drug/solvent/aberran*/etc. (2) Key terms such as **observation**, **fail***, **problem**, and **quality** were removed with no attempt to modify or refine them. Mylan made these extensive QA-Testing term changes even despite that evidence in their limited 12 search term analysis showed responsive documents. 30 of the 73 (41%) of the responsive documents that were identified in the May 8th letter as responsive were for the 4 terms from the QA-Testing list. Indeed, Plaintiffs find it wholly inconsistent and arbitrary that Mylan dropped **fail*** without attempting any modifications, while **detect*** was preserved.



Primary Search Terms were run in conjunction with the corresponding Modifier Search Terms across all designated Mylan custodians. The results of this sample search are summarized in the following chart:

Primary Term	Total Hits	Time Period	Total Docs Captured (one week)	Sample Set Reviewed	Responsive	Tr[illegible] Hit	Incidental Hit
Blood	108,332	February 2013	316	100	0		0
cGMP or (current pre/5 manufacturing) or GMP*	784,289	July 2012	393	100	13	10	3
Chromato*	522,652	December 2018	1,735	100	20	5	15

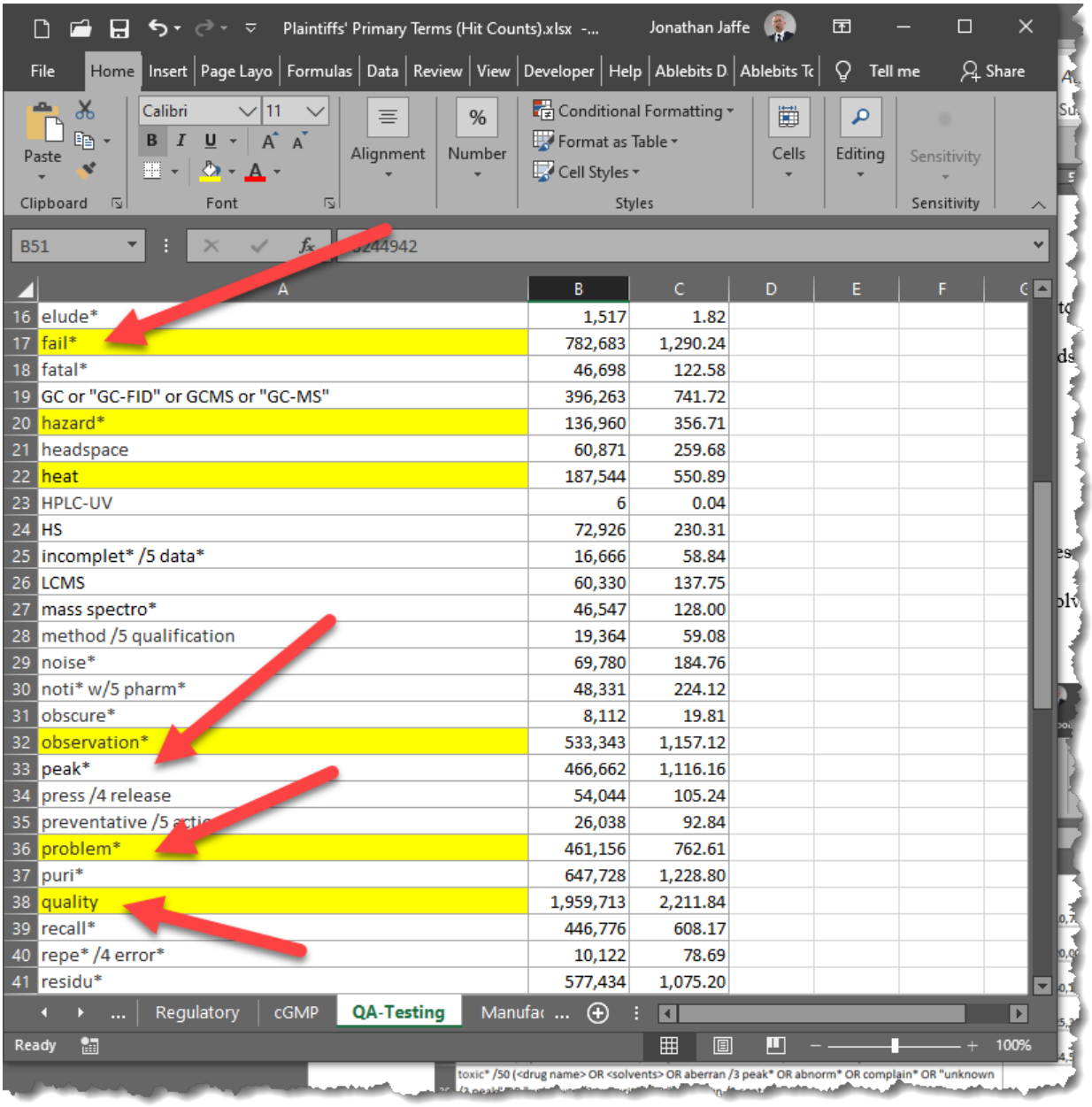
Delete/remove/ trash/shred	1,308,948	October 2017	2,116	100	3		3
Detect	517,464	January 2016	1,662	100	2	0	2
Error	1,051,498	May 2018	1,504	100	5	0	5
Fail	782,683	April 2011	586	100	3	0	3
Patrice Hall	104,651	September 2013	165	100	8	0	8



PGABR Primary Terms Counter-Proposal (Hit Counts).xlsx - Excel — Jonathan Jaffe

	A	B	C
34	risk* /50 (<drug name> OR <solvents> OR aberran /3 peak* OR abnorm* OR complain* OR "unknown /3 peak" OR "unknown /3 spike" OR "unknown /3 impurit*" OR "unknown /3 contamin*")	210,727	664.78
35	signal* /50 (<drug name> OR <solvents> OR aberran /3 peak* OR abnorm* OR complain* OR "unknown /3 peak" OR "unknown /3 impurit*" OR "unknown /3 contamin*")	20,007	54.34
36	spectro* /50 (<drug name> OR <solvents> OR aberran /3 peak* OR abnorm* OR complain* OR "unknown /3 peak" OR "unknown /3 impurit*" OR "unknown /3 contamin*")	40,174	236.21
37	spike* /50 (<drug name> OR <solvents> OR aberran /3 peak* OR abnorm* OR complain* OR "unknown /3 peak" OR "unknown /3 impurit*" OR "unknown /3 contamin*")	25,380	84.60
38	suitab* /50 (<drug name> OR <solvents> OR aberran /3 peak* OR abnorm* OR complain* OR "unknown /3 peak" OR "unknown /3 impurit*" OR "unknown /3 contamin*")	134,529	387.07
39	toxic* /50 (<drug name> OR <solvents> OR aberran /3 peak* OR abnorm* OR complain* OR "unknown /3 peak" OR "unknown /3 impurit*" OR "unknown /3 contamin*")	44,403	155.75
40			
41	NOTES:		
42	REMOVED:		
43	fail*		
44	observation		
45	problem		
46	quality		
47	headspace		
48	unknown* or unk or unks		
49	validat*		
50	aberran* /50 abnorm* /50 complain* /50 peak* used as modifiers rather than search terms		
51			
52			

Regulatory | cGMP | QA-Testing | Manufacturing



Manufacturing Terms

On the Manufacturing terms, Mylan honed in on the term **recycl***. Once again, Mylan egregiously limited **recycl*** to where it appears to be within two words of the literal word **solvent** not any specific solvents. This eliminated 99.9% of the prior hits, reducing the hit count from 890,501 documents to 1,026. As Mylan and the Court are well aware, the FDA cited the recycling of solvents as a key concern in how the carcinogen NDMA may have been introduced into

Valsartan.[2] Although clearly a drastic reduction of 889K+ documents, Mylan did not sample this term in their letter.

Once again, Mylan drastically seeks to change a central term. Note that even though 99.9% of the hits were removed, less than 50% of the actual burden (the data size as evidenced by the second column) was removed. In other words, the 889K+ documents collectively take less hard drive space than the 1,026 that remain.

33	recycl*	890,501	1,095.68

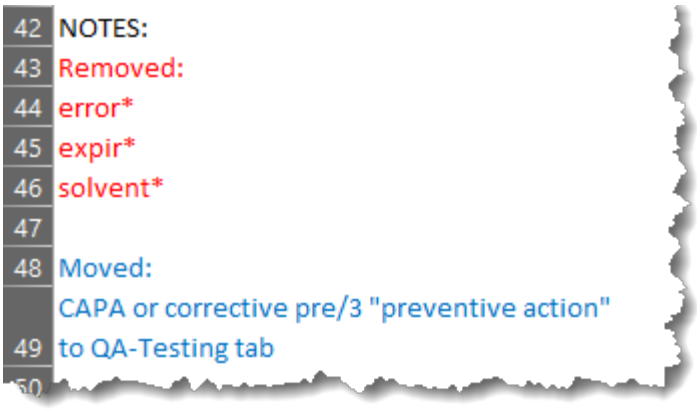
30	recycl* /2 solvent AND <drug name>	1,026	669.56

Although the modification to **recycl*** was the most insidious change, the wholesale removal of **error***, **expir*** and **solvent*** without any justification or analysis is equally alarming to Plaintiffs.

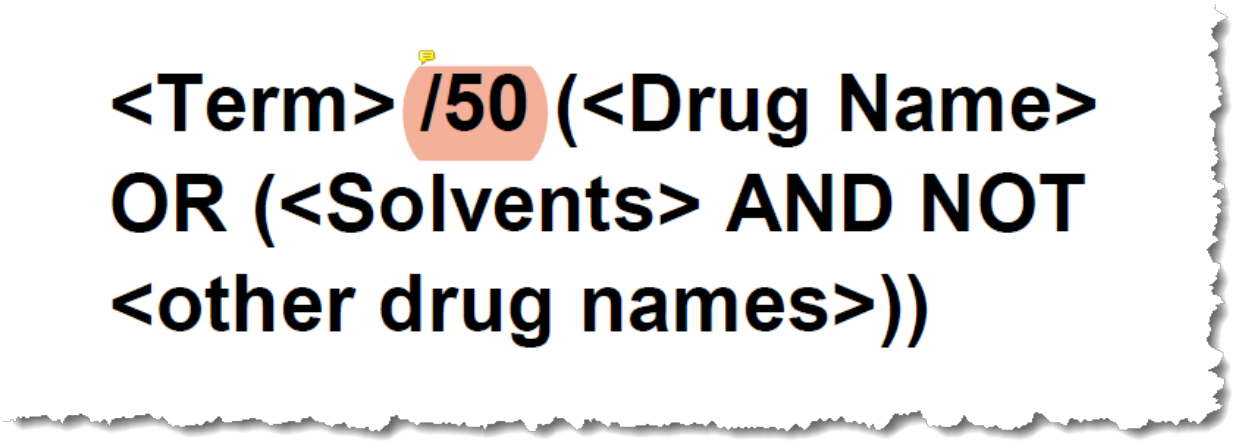
21	error*	1,051,498	1,515.52
22	esterficat*	73	0.18
23	expir*	330,575	933.63

39	solvent*	554,795	1,167.36

2 "In addition to these risks, our letter emphasizes the possibility of contaminated raw materials, including and especially solvents and catalysts (**particularly when these are reused**). Manufacturers should determine whether the raw materials they use to make drugs **were recycled**, meaning previously used, even if it is not disclosed by their supplier." (emphasis added) - https://www.fda.gov/news-events/press-announcements/fda-statement-agencys-list-known-nitrosamine-free-valsartan-and-arb-class-medicines-part-agencys accessed May 11, 2020 at 1:14 pm ET.



Proximity Restrictions on Regulatory, cGMP, QA-Testing, Manufacturing and Medications



Mylan has also, without apparent analysis, blanket restricted[3] search terms to have to appear within 50 words of the drug name or solvent across Regulatory, cGMP, QA-Testing, Manufacturing and Medications. The agreed to original Court order had no such restriction. Plaintiffs believe that such a proximity restriction is wholly inappropriate, particularly when applied to in such a blanket manner.

Mr. Jaffe has pointed out to Plaintiffs that such proximity restrictions would eliminate any hits where the term and modifier were in different parts of the document. For example:

[3] Either through the use of modifiers applied to the entire set or explicitly as additions to the primary terms

(1) An email whose subject is Valsartan and whose body contains the targeted search term.

(2) An email whose subject / body contains the term Valsartan and whose attachment is entitled with or contains within the targeted search term.

(3) A document in a Valsartan testing folder that mentions the targeted search term.

(4) A PowerPoint entitled Valsartan contamination that mentions the targeted search term in one or more slides.

The wholesale blanket exclusion of any of the above examples is improper.

Mr. Jaffe has also pointed out that even where proximity may not wholly eliminate a hit, 50 words is grossly insufficient. For example, if there is an email with a heading in the body called Valsartan Testing. An average paragraph is 100-200 words. So that means that the targeted search term must appear within the first half (or possibly first quarter) of the first paragraph or that both terms need to appear within the same half/quarter of the paragraph. For this reason, Plaintiffs find all of the /50 substitutions to be flawed. This paragraph alone is 98 words. Single spaced, an average page holds 1,000 words.

Once again, Mylan included a massive change with significant ramifications without any apparent analysis or justification.

Mylan complains about the volume of emails, but Mylan's strategy for reducing that volume appears to be to remove or arbitrarily modify the terms that are core to the allegations and arbitrarily introduce proximity requirements wholesale that have scant relationship to responsiveness.

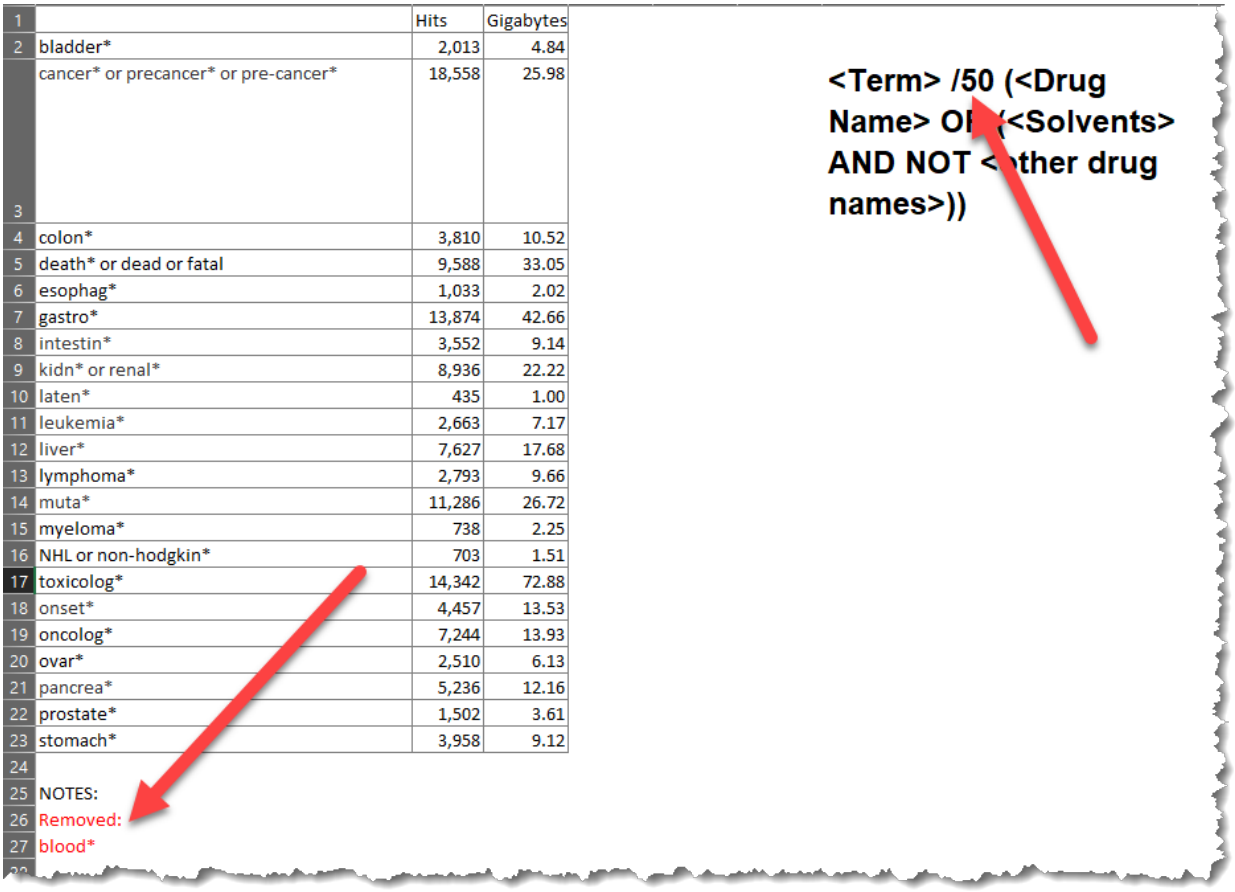
Medical Conditions Terms

On the medical conditions terms, by eliminating the term **blood*** and adding in the /50 proximity restriction, 86% of the hits are removed. Again, Plaintiffs believe Mylan has not been analytical regarding the impact of the proposed changes. Mylan lists search totals on the Plaintiff hit counts sheet, but neglects to include those totals on their proposal hit counts sheet.[4] This creates the illusion that these medical search terms have not been substantially modified, but from the data it is clear the magnitude of the changes was significant, *i.e.* the proximity modifications have substantially reduced the volume of the results. Only the term **blood*** was included in the sample set of 12 terms. To Plaintiffs' knowledge, Mylan has not performed any due diligence that the documents eliminated are unlikely to be responsive and relevant.

Plaintiffs take issue with the wholesale elimination of **blood*** with no attempt to refine that term should Mylan have found it overly broad. The Court and Mylan are well aware that Valsartan is a blood pressure medication, that NDMA is detected through a blood test, and that NDMA reaches the liver through the bloodstream. The original item count for the term **blood*** was lower than numerous terms that Mylan retained even accounting for Mylan's modifications, for instance, **temperature** in manufacturing.

[4] Plaintiffs 86% is based upon a comparison of the total data size reduction.

	Term	Item Count	GB volume
2	bladder*	18,332	64.42
3	blood*	108,332	373.81
4	cancer* or precancer* or pre-cancer*	85,387	148.03
5	colon*	40,380	152.67
6	death* or dead or fatal	83,491	206.61
7	esophag*	9,499	25.77
8	gastro*	73,771	174.15
9	intestin*	29,573	70.99
10	kidn* or renal*	60,512	157.42
11	laten*	7,077	20.52
12	leukemia*	15,425	33.14
13	liver*	59,062	157.39
14	lymphoma*	22,591	54.55
15	muta*	62,600	135.60
16	myeloma*	9,142	20.53
17	NHL or non-hodgkin*	5,583	25.19
18	toxicolog*	88,050	272.68
19	onset*	36,463	104.57
20	oncolog*	41,635	109.11
21	ovar*	22,807	62.21
22	pancrea*	35,491	94.71
23	prostate*	16,246	36.55
24	stomach*	29,498	83.72
25	**Search total**	**288,911**	**764.53**
26	**Search total (without highlighted terms)**	**286,037**	**758.16**
27			



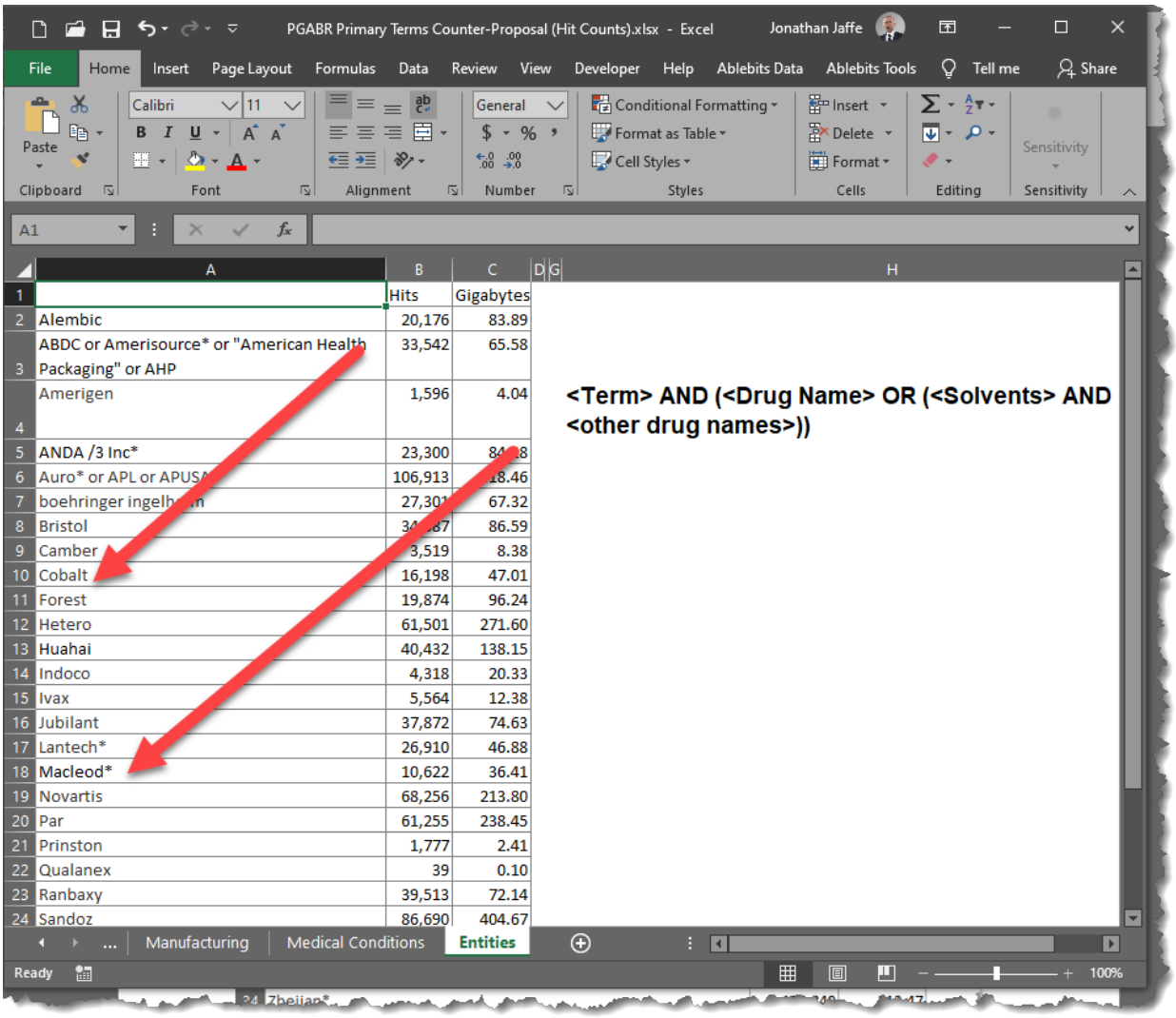
		Hits	Gigabytes
2	bladder*	2,013	4.84
3	cancer* or precancer* or pre-cancer*	18,558	25.98
4	colon*	3,810	10.52
5	death* or dead or fatal	9,588	33.05
6	esophag*	1,033	2.02
7	gastro*	13,874	42.66
8	intestin*	3,552	9.14
9	kidn* or renal*	8,936	22.22
10	laten*	435	1.00
11	leukemia*	2,663	7.17
12	liver*	7,627	17.68
13	lymphoma*	2,793	9.66
14	muta*	11,286	26.72
15	myeloma*	738	2.25
16	NHL or non-hodgkin*	703	1.51
17	toxicolog*	14,342	72.88
18	onset*	4,457	13.53
19	oncolog*	7,244	13.93
20	ovar*	2,510	6.13
21	pancrea*	5,236	12.16
22	prostate*	1,502	3.61
23	stomach*	3,958	9.12
24			
25	NOTES:		
26	Removed:		
27	blood*		

Entities Terms

Even on the entities terms, Mylan is not transparent regarding the proposed changes. Unlike on the other sheets, there is no footnote as to which terms were removed. There is something striking at first glance upon closer examination. Somehow, all of the remaining terms have decreased hit counts even though at first glance the terms and modifiers categories are the same as proposed on the original sheet. This brings the discussion back to inspect closer the modified modifier terms list as proposed by Mylan. Entity terms removed are highlighted in yellow below.[5]

[5] Plaintiffs are unclear whether the removal of Mylan was intended to apply only to Mylan or across all Defendants. As already provided for in the Ordered search terms, an entity is not required to search for itself. Further, Plaintiffs do not concur on the wholesale removal of distribut* which references Distributors generically.

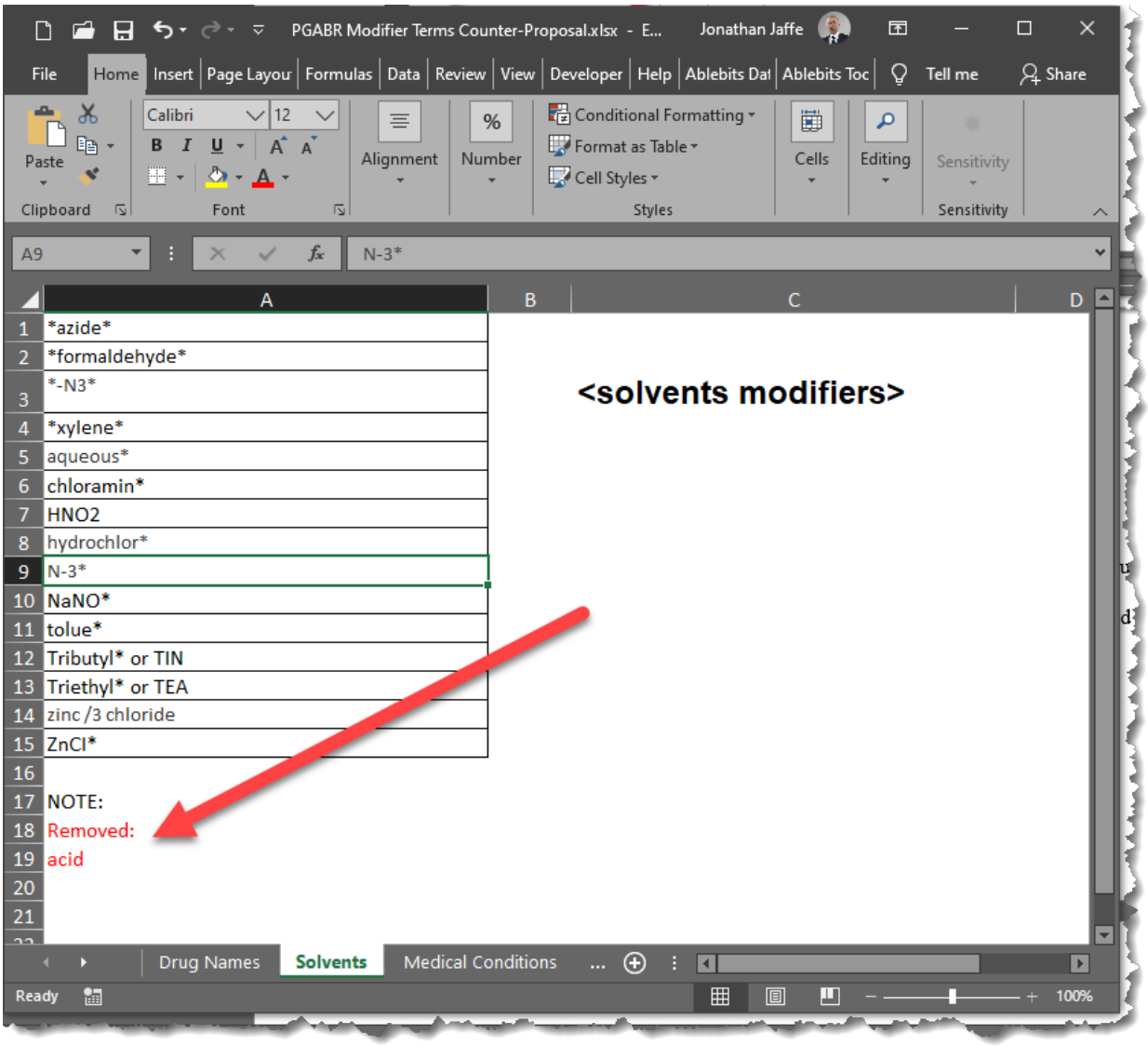
	Term	Item Count	GB volume
2	Alembic	20,500	83.63
3	ABDC or Amerisource* or "American Health Packaging" or AHP	32,842	57.91
4	Amerigen	1,612	3.89
5	ANDA	232,819	545.89
6	Auro* or APL or APUSA	108,001	401.50
7	boehringer ingelheim	28,665	67.07
8	Bristol	36,897	89.98
9	Camber	3,654	8.25
10	Cobalt	16,077	44.30
11	distribut*	1,147,060	1,689.60
12	Forest	20,710	92.52
13	Hetero	63,687	267.95
14	Huahai	40,639	134.61
15	Indoco	4,526	19.84
16	Ivax	5,784	12.62
17	Jubilant	39,596	73.27
18	Lantech*	26,865	45.14
19	Macleod*	11,064	37.42
20	Matrix	189,741	533.61
21	Mylan	2,012,821	2,273.28
22	Novartis	73,385	214.47
23	Par	67,482	242.76
24	Prinston	1,747	2.40
25	Qualanex	61	0.16
26	Ranbaxy	42,074	72.34
27	Sandoz	92,632	405.79
28	Syncore	214	0.48
29	Synthon	23,420	189.15
30	Teva	183,201	536.62
31	Torrent	73,868	208.16
32	Unichem	52,421	198.32
33	Watson	32,351	78.85
34	Zhejian*	100,840	313.47
35	ZHP	700	1.46
36	**Search total**	**2,030,983**	**2,283.52**
37	**Search total (without highlighted terms)**	**629,220**	**1,228.80**
38			



	A	B	C
1		Hits	Gigabytes
2	Alembic	20,176	83.89
3	ABDC or Amerisource* or "American Health Packaging" or AHP	33,542	65.58
4	Amerigen	1,596	4.04
5	ANDA /3 Inc*	23,300	84.38
6	Auro* or APL or APUSA	106,913	18.46
7	boehringer ingelh m	27,301	67.32
8	Bristol	34,187	86.59
9	Camber	3,519	8.38
10	Cobalt	16,198	47.01
11	Forest	19,874	96.24
12	Hetero	61,501	271.60
13	Huahai	40,432	138.15
14	Indoco	4,318	20.33
15	Ivax	5,564	12.38
16	Jubilant	37,872	74.63
17	Lantech*	26,910	46.88
18	Macleod*	10,622	36.41
19	Novartis	68,256	213.80
20	Par	61,255	238.45
21	Prinston	1,777	2.41
22	Qualanex	39	0.10
23	Ranbaxy	39,513	72.14
24	Sandoz	86,690	404.67

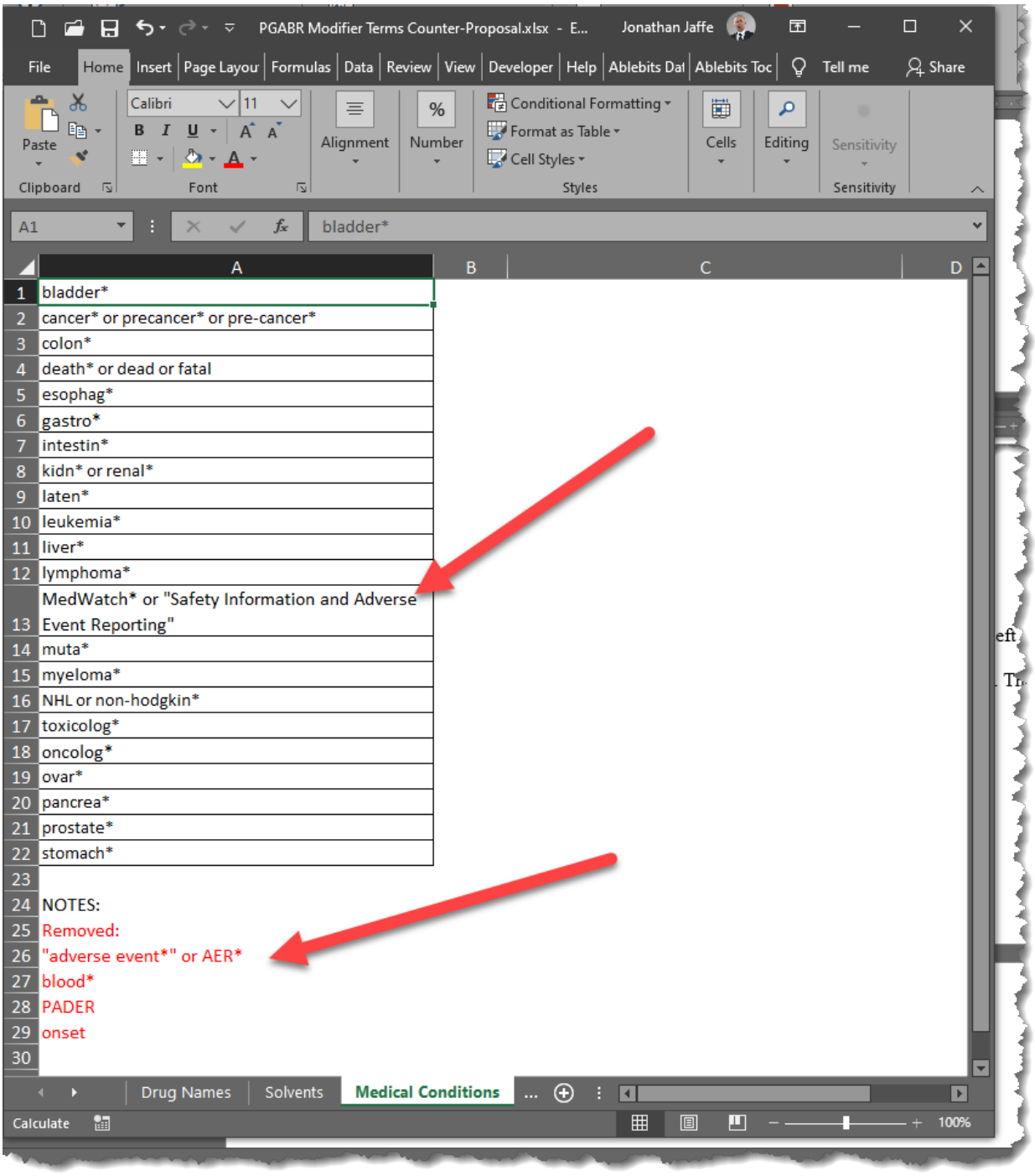
Solvent Modifiers

The term **acid** was removed from the solvent modifiers. Plaintiffs have not been provided any justification or analysis that led to the removal of the modifier term **acid**. There appears to have been no attempt to add **acid** back into the primary terms list with modifications.



Medical Condition Modifiers

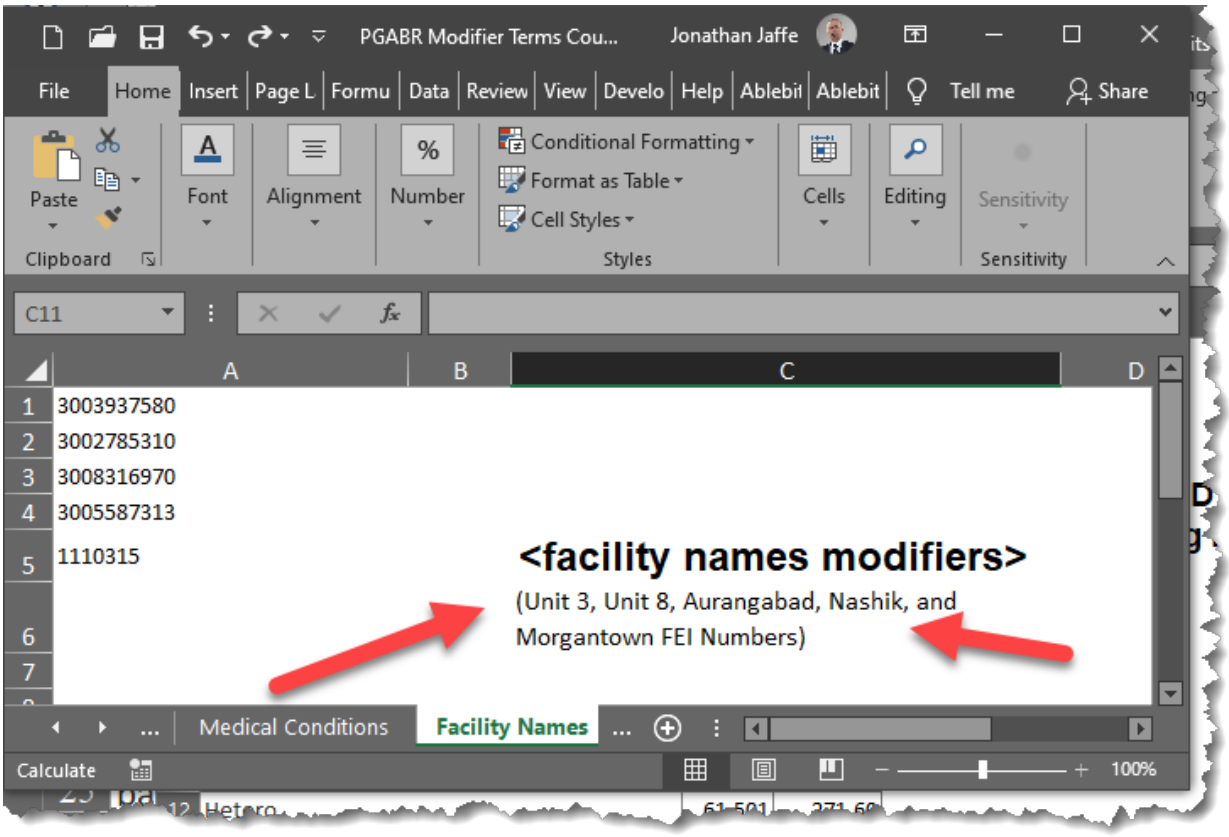
There were a set of medical modifiers removed. Mylan's proposed changes left in **Safety Information and Adverse Event Reporting** but remove **AER** and **adverse event***. That appears to be inconsistent and without apparent justification (they are the same term). Plaintiffs note that on Defendants proposals for search terms going back to last November, Defendants repeatedly proposed the validity of **blood*** with other medical terms such as **carcin*** and ***cancer*** and **liver***. Plaintiffs find it arbitrary that Mylan has removed **blood*** without considering this subset.



Facility Names Modifiers

On the facility names modifiers, Mylan **only includes the FEI numbers** and not the names. Other Defendants have already agreed to much broader identification, based upon the common and actual usage at their respective companies. Plaintiffs insist that at the very least Unit

3, Unit 8, Aurangabad, Nashik and Morgantown must be included and that the omission of the common names by which these facilities are referred, based upon the actual usage at Mylan, is an omission inconsistent with good faith negotiations.



Mylan's Letter of May 8th – Search Term Sample Analysis for Responsiveness

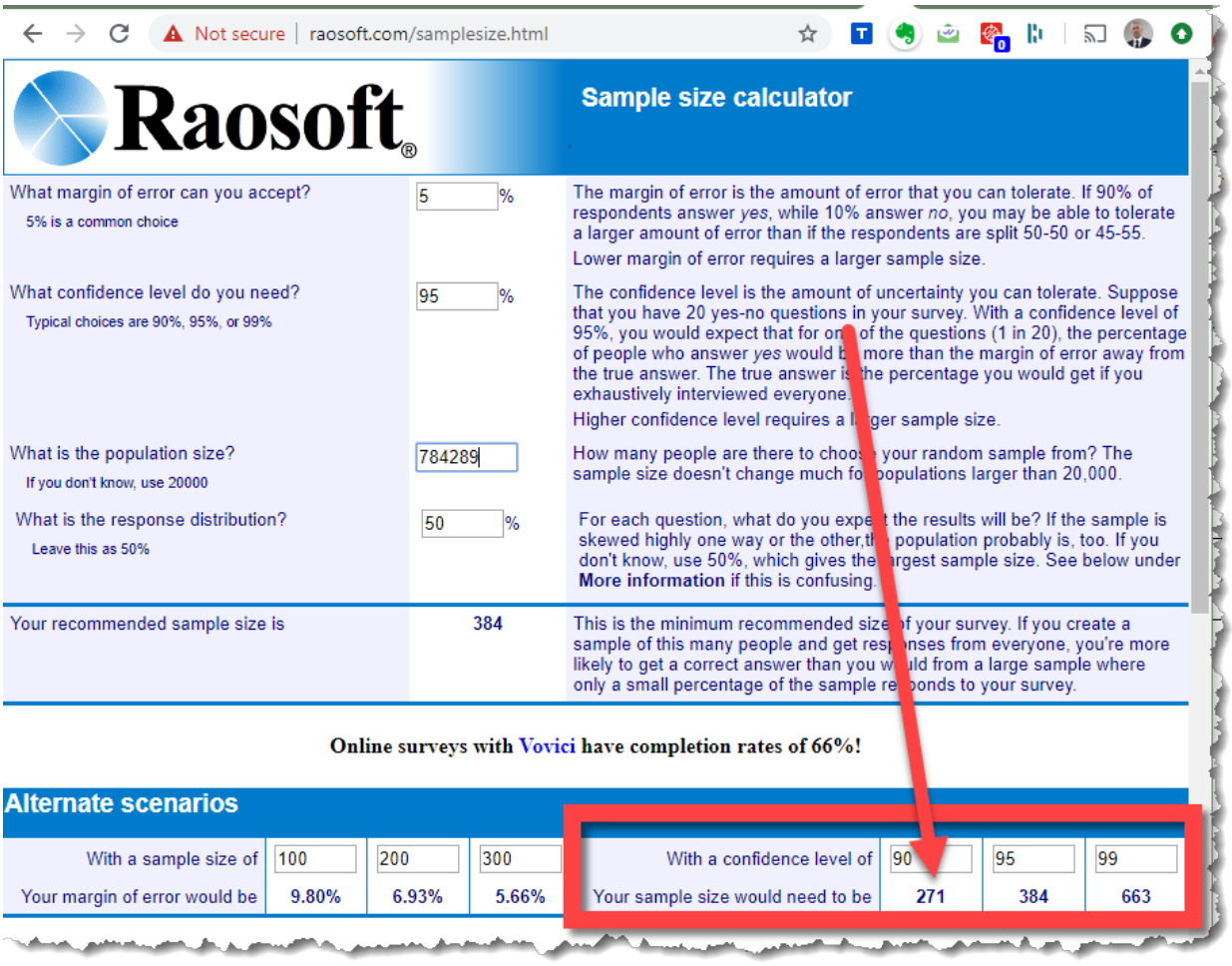
Next, we address the 12 search term sample analysis Mylan performed as articulated in Mylan's letter of May 8th.

First, how did Mylan pick the terms? From the letter, Mylan chose terms that were "facially overbroad" **NOT** terms (or modifiers) that were restricted[6] or eliminated in the "Revised ESI Search Term" set, such as **DMF**. This selection created a skewed sample inappropriate for generalization.

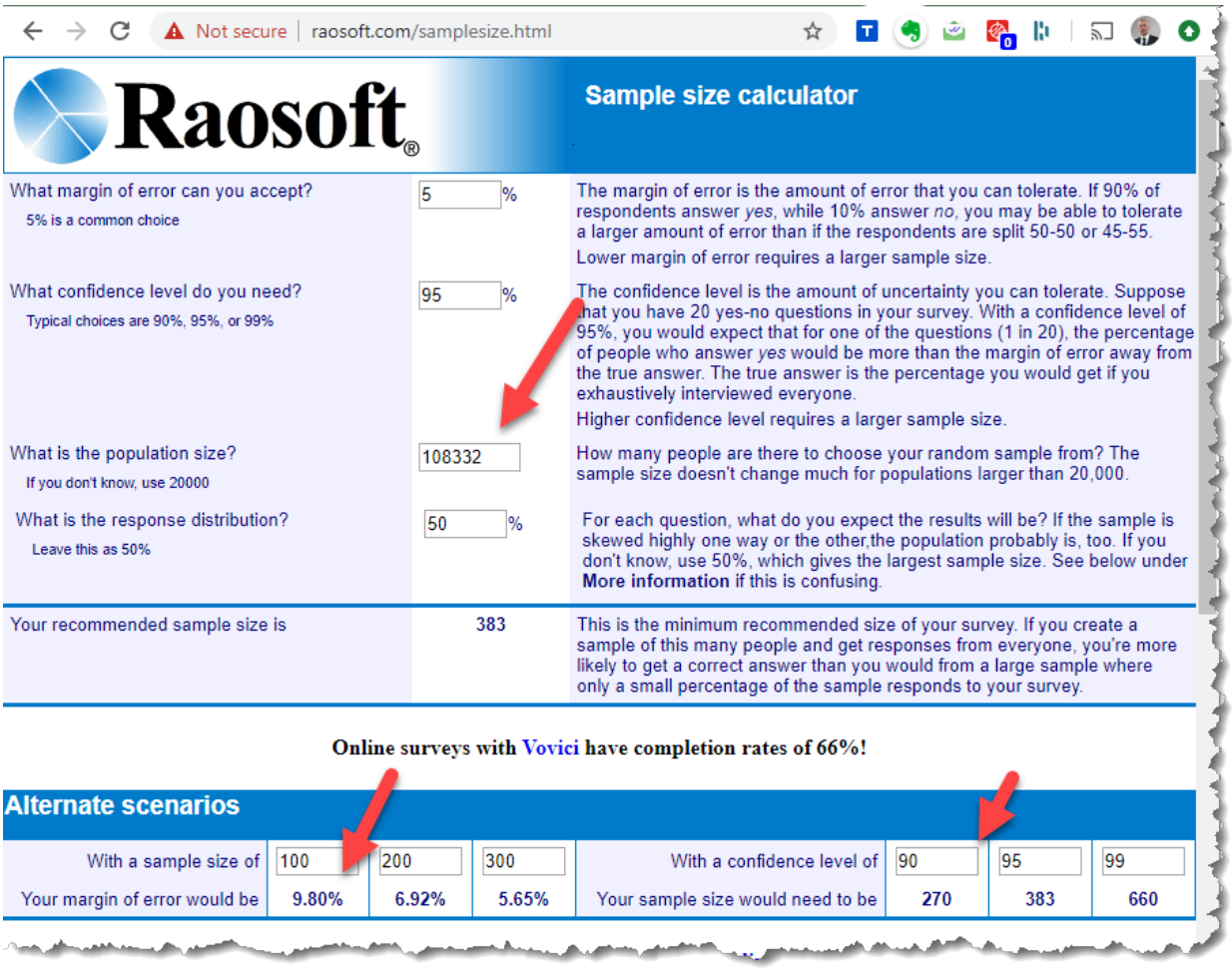
[6] whether by addition of more conditions or proximity restraints

Next, Mylan's letter claims that the samples represent a "statistically representative sample size." That is an exceptionally vague statement. For example, for the 784,289 hits on **cGMP**, Mylan only reviewed 100 documents. To reach a confidence level of 90% with a 5% margin of error, Mylan would have had to have reviewed 271 documents. To reach the more established 95% confidence level, Mylan would have had to review 384 documents. Reviewing only 100 documents, has a margin of error of almost 10%.

Primary Term	Total Hits	Time Period	Total Docs Captured (one week)	Sample Set Reviewed	Responsive	True Hit	Incidental Hit
Blood	108,332	February 2013	316	100	0	0	0
cGMP or (current pre/5 manufacturing) or GMP*	784,289	July 2012	393	100	13	10	3
Chromate*	522,652	December 2018	1,735	100	20	5	15



Although it may seem counter-intuitive, 100 documents is just about as equally insufficient a sample for a term like **blood*** which had 108,332 hits.



Mr. Jaffe has pointed out that the random selection of the choice of week for Patrice Hall and Dipesh Shah is inappropriate. A random week does not invalidate these Authors/Inspectors selection when relevant communications are highly time dependent and linked to the dates of inspection or publication. Clearly, given the small sample, this could be a reasonable explanation for why Dipesh Shah had no responsive documents in Nov 2016, and Patrice Hall had 8 in Sept 2013.

Patrice Hall	104,651	September 2013	165	100	**8**	**0**	**8**
Inspect	682,542	August 2019	1,366	100	**13**	**4**	**9**
Investigat*	780,241	June 2014	2,509	100	**6**	**6**	**0**
Recycl*	890,501	April 2017	5,386	100	**0**	**0**	**0**
Dipesh Shah	240,952	November 2016	242	100	**0**	**0**	**0**

In other words, while Mylan's argument that only 5 out of the 73 documents not captured in the revised terms may appear to be a facially compelling argument to project this conclusion to all the terms, this is predicated upon the false foundation assumption that the results from all these terms are representative. Since Mylan's sample is not a representative sample, the analysis is fatally flawed.

Mylan's terms are skewed toward the facially overbroad. Mr. Jaffe took the liberty of sorting the Mylan chart by hits and looking at the % each term represented to the overall number of hits in these 12 terms. The first 3 terms, which are cGMP terms that Plaintiffs have already agreed to modify conditionally, represent 42% of all the hits. Including the term **fail**, which Plaintiffs also agree to conditionally modify, coversgreater than 50% of the hits by modifying 4 terms.

Term	Hits	% of total
Delete/remove/trash/shred	1,308,948	17%
Error	1,051,498	14%
Recycl*	890,501	11%
cGMP or (current pre/5 manufacturing) or GMP*	784,289	10%
Fail	782,683	10%
Investigat*	780,241	10%
Inspect*	682,542	9%
Chromato*	522,652	7%
Detect	517,464	7%
Dipesh Shah	240,952	3%
Blood	108,332	1%
Patrice Hall	104,651	1%
	7,774,753	

DMF would have represented 750,698 hits by Mylan's count. In other words, just shy of 95% of the hits of the original term were dropped by the exclusion of this core term alone.

*dimethylformamide OR DMF		791,959
*dimethylformamide	41,261	96.33

But, equally disturbing, the simple changes to **adverse event** dropped 62,858 hits or by 98.8%.

Term	Item Count	GB volume
("adverse event*" OR AER) and (<drug name> OR <solvents> OR <facility names>)	63,631	255.28

	Hits	Gigabytes
("adverse event*" or AER) /50 <drug name> /50 <medical conditions>	773	0.75

So, rather than sample the terms that it did, why didn't Mylan sample these much more significant changes for responsiveness?

Further, **Chromato*** is clearly responsive.

Primary Term	Total Hits	Time Period	Total Docs Captured (one week)	Sample Set Reviewed	Responsive	True Hit	Incidental Hit
Blood	108,332	February 2013	316	100	**0**	**0**	**0**
cGMP or (current pre/5 manufacturing) or GMP*	784,289	July 2012	393	100	**13**	**10**	**3**
Chromato*	522,652	December 2018	1,735	100	**20**	**5**	**15**

In fact, 60 / 73 (82%) of the responsive hits fall under the remaining 8 terms.

Mr. Jaffe has done some simple math.

Inspect* had 1,366 hits on the sampled week with 682,542 total hits. Mylan flagged 4 true hits. The sampled week was just shy of 1/500th of the total hits. So, multiple by ~499, and factor in the 10% margin of error, and we get between 1,798 and 2,198 expected true hits that would have been missed by the search term. Though Mylan argues that the 73 search hits having 93% of them hit other terms gives them confidence, as explained above, projecting a sample of 73 to 7.8MM is far past any accepted statistical standard.[7] 73 is not the total number of "true hits" – that is the responsive size. There were only 25 true hits across the set.

That is clearly insufficient to draw any conclusions extrapolating to the whole set.

[7] Mr. Jaffe has calculated that using a minimum confidence level of 90% and margin of error of 5%, a statistically valid sample size would have to be 271 documents. Relying on 73 documents has a margin of error of 9.63% under a 90% confidence level and 11.47% margin of error under a 95% confidence level, neither meeting minimum acceptable statistical standards. Mr. Jaffe has further explained that using this set to project would also assume that the set is truly representative. Since the selection of the documents was limited to only 12 search terms, and not a representative sample of the population of documents responsive to hits across all search terms, any projections to the whole set does not meet any acceptable statistical standard.

Term	Hits	Hits for Sampled Week	True Hits	Multiplier	Projected Hits Missed	Hits Missed Range
Delete/remove/trash/shred	1,308,948	2,116	0	618.5954631	-	[0, 0]
Error	1,051,498	1,504	0	699.1343085	-	[0, 0]
Recycl*	890,501	5,386	0	165.3362421	-	[0, 0]
cGMP or (current pre/5 manufacturing) or GMP*	784,289	393	10	1995.64631	19,956	[17,960, 21,952]
Fail	782,683	586	0	1335.636519	-	[0, 0]
Investigat*	780,241	2,509	6	310.9768832	1,866	[1,679, 2,052]
Inspect*	682,542	1,366	4	499.6647145	1,999	[1,798, 2,198]
Chromato*	522,652	1,735	5	301.2403458	1,506	[1,355, 1,656]
Detect	517,464	1,662	0	311.3501805	-	[0, 0]
Dipesh Shah	240,952	242	0	995.6694215	-	[0, 0]
Blood	108,332	316	0	342.8227848	-	[0, 0]
Patrice Hall	104,651	165	0	634.2484848	-	[0, 0]
	7,774,753					

This is not even including the responsive hits. Mr. Jaffe has calculated projections of missed responsive hits.

Term	Hits	Hits for Sampled Week	Responsive Hits	Multiplier	Projected Hits Missed	Range
Delete/remove/trash/shred	1,308,948	2,116	3	618.5954631	1,856	[1670, 2041]
Error	1,051,498	1,504	5	699.1343085	3,496	[3146, 3845]
Recycl*	890,501	5,386	0	165.3362421	-	[0, 0]
cGMP or (current pre/5 manufacturing) or GMP*	784,289	393	13	1995.64631	25,943	[23349, 28537]
Fail	782,683	586	3	1335.636519	4,007	[3606, 4407]
Investigat*	780,241	2,509	6	310.9768832	1,866	[1679, 2052]
Inspect*	682,542	1,366	13	499.6647145	6,496	[5846, 7145]
Chromato*	522,652	1,735	20	301.2403458	6,025	[5422, 6627]
Detect	517,464	1,662	2	311.3501805	623	[560, 684]
Dipesh Shah	240,952	242	0	995.6694215	-	[0, 0]
Blood	108,332	316	0	342.8227848	-	[0, 0]
Patrice Hall	104,651	165	8	634.2484848	5,074	[4566, 5581]
	7,774,753				55,385	[49846, 60923]

So, even using Mylan's flawed review as previously discussed and outlined, Mr. Jaffe estimated Plaintiffs would be missing roughly 50-60 thousand responsive documents on modifications to the twelve sampled "facially overbroad" terms. Excluding the 4 terms that comprise the 42% of the original hits, modifications to the remaining terms would be 90% of the missing projected hits, or 45-55 thousand expected responsive documents.

Taking all of this into account, Plaintiffs will agree to the conditional modifications identified as acceptable herein, including the cGMP modifications, and fail*. Plaintiffs do not agree to any other modifications, and believe that at this late stage, just two months before the rolling productions are to begin, that the Defendants should turn their attention to reviews and preparation of the ESI for production.

Please let us know if you would like to discuss further, or if you will agree to end this process with agreement to the conditional modifications Plaintiffs have agreed to.

Very Truly Yours

Adam M. Slater